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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA
SACRAMENTO DIVISION

COUNTY OF YUBA,
a political subdivision of the
State of California; THE PEOPLE
OF THE STATE OF CALIFORNIA,
acting by and through the COUNTY
OF YUBA,

Plaintiffs,

vs.

AMERISOURCEBERGEN DRUG
CORPORATION; CARDINAL
HEALTH, INC.; McKESSON
CORPORATION; PURDUE PHARMA
L.P.; PURDUE PHARMA, INC.; THE
PURDUE FREDERICK COMPANY,
INC.; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; TEVA
PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON &
JOHNSON; JANSSEN
PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a
JANSSEN PHARMACEUTICALS,
INC.; JANSSEN PHARMACEUTICA

Case No.: _____

**COMPLAINT FOR DAMAGES
AND DEMAND FOR JURY
TRIAL**

- (1) Public Nuisance;
- (2) Violations of Racketeer
Influenced and Corrupt
Organizations Act (RICO), 18
U.S.C. § 1961 et seq.;
- (3) Violations of 18 U.S.C. § 1962
et seq.;
- (4) Violations of the California
False Advertising Act, Cal. Bus.
& Prof. Code § 17500 et seq.;
- (5) Negligent Misrepresentation;
- (6) Fraud and Fraudulent
Misrepresentation; and
- (7) Unjust Enrichment.

INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.;
NORAMCO, INC.; ENDO HEALTH
SOLUTIONS INC.; ENDO
PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS
PLS; WATSON
PHARMACEUTICALS, INC. n/k/a
ACTAVIS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS
LLC; ACTAVIS PHARMA, INC. f/k/a
WATSON PHARMA, INC.;
MALLINCKRODT PLC;
MALLINCKRODT LLC; INSYS
THERAPEUTICS, INC; CVS
HEALTH CORP.; THE KROGER CO.;
RITE AID OF MARYLAND, INC.;
THRIFTY PAYLESS, INC.;
WALGREENS BOOTS ALLIANCE,
INC.; and WAL-MART, INC.

Defendants.

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1 7. The County is responsible for the public health, safety and welfare of
2 its citizens.

3 8. The County has declared, *inter alia*, that opioid abuse, addiction,
4 morbidity and mortality have created a serious public health and safety crisis, and
5 is a public nuisance, and that the diversion of legally produced controlled substances
6 into the illicit market causes or contributes to this public nuisance.

7 9. The distribution and diversion of opioids into California (“the State”),
8 and into Yuba County and surrounding areas (collectively, “Plaintiffs’
9 Community”), created the foreseeable opioid crisis and opioid public nuisance for
10 which Plaintiffs here seek relief.

11 10. Plaintiffs directly and foreseeably sustained all economic damages
12 alleged herein. Defendants’ conduct has exacted a financial burden for which the
13 Plaintiffs seek relief. Categories of past and continuing sustained damages include,
14 *inter alia*,: (1) costs for providing medical care, additional therapeutic, and
15 prescription drug purchases, and other treatments for patients suffering from opioid-
16 related addiction or disease, including overdoses and deaths; (2) costs for providing
17 treatment, counseling, and rehabilitation services; (3) costs for providing treatment
18 of infants born with opioid-related medical conditions; (4) costs associated with law
19 enforcement and public safety relating to the opioid epidemic; (5) costs associated
20 with providing care for children whose parents suffer from opioid-related disability
21 or incapacitation and (6) costs associated with The County having to repair and
22 remake its infrastructure, property and systems that have been damaged by
23 Defendants’ actions, including, *inter alia*, its property and systems to treat addiction
24 and abuse, to respond to and manage an elevated level of crime, to treat injuries,
25 and to investigate and process deaths in Plaintiffs’ Community. These damages
26 have been suffered, and continue to be suffered, directly by the Plaintiffs.

27 11. Plaintiffs also seek the means to abate the epidemic created by
28 Defendants’ wrongful and/or unlawful conduct.

1 12. The People have standing to bring an action for the opioid epidemic
2 nuisance created by Defendants. Cal. Civ. Proc. Code § 731 (“A civil action may
3 be brought in the name of the people of the State of California to abate a public
4 nuisance, as defined in Section 3480 of the Civil Code, by the . . . county counsel
5 of any county in which the nuisance exists.”).

6 13. The County has standing to bring an action for damages incurred to its
7 property by the public nuisance created by Defendants. Cal. Civ. Proc. Code § 731
8 (“An action may be brought by any person whose property is injuriously affected, .
9 . . and by the judgment in that action the nuisance may be enjoined or abated as well
10 as damages recovered therefor.”).

11 14. The People have standing to bring this claim for injunctive relief and
12 civil penalties under the California False Advertising Act. Cal. Bus. & Prof. Code
13 §§ 17535, 17536.

14 15. The County has standing to recover damages incurred as a result of
15 Defendants’ actions and omissions. Cal. Gov’t Code § 23004(a). The County has
16 standing to bring claims under the federal RICO statute, pursuant to 18 U.S.C. §
17 1961(3) (“persons” include entities which can hold legal title to property) and 18
18 U.S.C. § 1964 (“persons” have standing).

19 **B. DEFENDANTS.**

20 **1. Manufacturer Defendants.**

21 16. The Manufacturer Defendants are defined below. At all relevant times,
22 the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into
23 the stream of commerce, labeled, described, marketed, advertised, promoted and
24 purported to warn or purported to inform prescribers and users regarding the
25 benefits and risks associated with the use of the prescription opioid drugs. The
26 Manufacturer Defendants, at all times, have manufactured and sold prescription
27 opioids without fulfilling their legal duty to prevent diversion and report suspicious
28 orders.

1 17. PURDUE PHARMA L.P. is a limited partnership organized under the
2 laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its
3 principal place of business in Stamford, Connecticut, and THE PURDUE
4 FREDERICK COMPANY, INC. is a Delaware corporation with its principal place
5 of business in Stamford, Connecticut (collectively, “Purdue”).

6 18. Purdue manufactures, promotes, sells, and distributes opioids such as
7 OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq
8 ER in the United States. OxyContin is Purdue’s best-selling opioid. Since 2009,
9 Purdue’s annual nationwide sales of OxyContin have fluctuated between \$2.47
10 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million.
11 OxyContin constitutes roughly 30% of the entire market for analgesic drugs
12 (painkillers).

13 19. CEPHALON, INC. is a Delaware corporation with its principal place
14 of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES,
15 LTD. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in
16 Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA
17 PHARMACEUTICALS USA, INC. (“Teva USA”) is a Delaware corporation and
18 is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired
19 Cephalon in October 2011.

20 20. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids
21 such as Actiq and Fentora in the United States. Actiq has been approved by the FDA
22 only for the “management of breakthrough cancer pain in patients 16 years and
23 older with malignancies who are already receiving and who are tolerant to around-
24 the-clock opioid therapy for the underlying persistent cancer pain.”⁴ Fentora has
25 been approved by the FDA only for the “management of breakthrough pain in
26

27
28 ⁴ *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral*
transmucosal lozenge, CII (2009),
https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.

1 cancer patients 18 years of age and older who are already receiving and who are
 2 tolerant to around-the-clock opioid therapy for their underlying persistent cancer
 3 pain.”⁵ In 2008, Cephalon pled guilty to a criminal violation of the Federal Food,
 4 Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs,
 5 and agreed to pay \$425 million.⁶

6 21. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to
 7 market and sell Cephalon products in the United States. Teva Ltd. conducts all sales
 8 and marketing activities for Cephalon in the United States through Teva USA and
 9 has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva
 10 USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all
 11 former Cephalon branded products through its “specialty medicines” division. The
 12 FDA-approved prescribing information and medication guide, which is distributed
 13 with Cephalon opioids, discloses that the guide was submitted by Teva USA, and
 14 directs physicians to contact Teva USA to report adverse events.

15 22. All of Cephalon’s promotional websites, including those for Actiq and
 16 Fentora, display Teva Ltd.’s logo.⁷ Teva Ltd.’s financial reports list Cephalon’s and
 17 Teva USA’s sales as its own, and its year-end report for 2012 – the year
 18 immediately following the Cephalon acquisition – attributed a 22% increase in its
 19 specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty
 20 sales,” including *inter alia* sales of Fentora®.⁸ Through interrelated operations like
 21

22 ⁵ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal*
 23 *tablet, CII* (2011),
https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

24 ⁶ Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to
 25 Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing
 (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

26 ⁷ *E.g.*, ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last visited
 27 Jan. 16, 2018).

28 ⁸ Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013),
http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

1 these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and
2 Teva USA. The United States is the largest of Teva Ltd.'s global markets,
3 representing 53% of its global revenue in 2015, and, were it not for the existence of
4 Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business
5 in the United States itself. Upon information and belief, Teva Ltd. directs the
6 business practices of Cephalon and Teva USA, and their profits inure to the benefit
7 of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva
8 Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

9 23. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania
10 corporation with its principal place of business in Titusville, New Jersey, and is a
11 wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey
12 corporation with its principal place of business in New Brunswick, New Jersey.
13 NORAMCO, INC. ("Noramco") is a Delaware company headquartered in
14 Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016.
15 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as
16 JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its
17 principal place of business in Titusville, New Jersey. JANSSEN
18 PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS,
19 INC., is a Pennsylvania corporation with its principal place of business in Titusville,
20 New Jersey. J&J is the only company that owns more than 10% of Janssen
21 Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's
22 products. Upon information and belief, J&J controls the sale and development of
23 Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen
24 Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen
25 Pharmaceutica, Inc., Noramco, and J&J are referred to as "Janssen."

26 24. Janssen manufactures, promotes, sells, and distributes drugs in the
27 United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic
28 accounted for at least \$1 billion in annual sales. Until January 2015, Janssen

1 developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER.
2 Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

3 25. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with
4 its principal place of business in Malvern, Pennsylvania. ENDO
5 PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health
6 Solutions Inc. and is a Delaware corporation with its principal place of business in
7 Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.
8 are referred to as “Endo.”

9 26. Endo develops, markets, and sells prescription drugs, including the
10 opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States.
11 Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in
12 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it
13 accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and
14 sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and
15 hydrocodone products in the United States, by itself and through its subsidiary,
16 Qualitest Pharmaceuticals, Inc.

17 27. ALLERGAN PLC is a public limited company incorporated in Ireland
18 with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired
19 ALLERGAN PLC in March 2015, and the combined company changed its name to
20 ALLERGAN PLC in January 2013. Before that, WATSON
21 PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the
22 combined company changed its name to Actavis, Inc. as of January 2013 and then
23 ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada
24 corporation with its principal place of business in Corona, California, and is a
25 wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson
26 Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a
27 Delaware corporation with its principal place of business in New Jersey and was
28 formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware

1 limited liability company with its principal place of business in Parsippany, New
2 Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them
3 to market and sell its drugs in the United States. Upon information and belief,
4 ALLERGAN PLC exercises control over these marketing and sales efforts and
5 profits from the sale of Allergan/Actavis products ultimately inure to its benefit.
6 ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis
7 Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
8 Laboratories, Inc. are referred to as “Actavis.”

9 28. Actavis manufactures, promotes, sells, and distributes opioids,
10 including the branded drugs Kadian and Norco, a generic version of Kadian, and
11 generic versions of Duragesic and Opana, in the United States. Actavis acquired the
12 rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began
13 marketing Kadian in 2009.

14 29. MALLINCKRODT, PLC is an Irish public limited company
15 headquartered in Staines-upon-Thames, United Kingdom, with its U.S.
16 headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability
17 company organized and existing under the laws of the State of Delaware.
18 Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC.
19 Mallinckrodt, PLC and Mallinckrodt, LLC are referred to as “Mallinckrodt.”

20 30. Mallinckrodt manufactures, markets, and sells drugs in the United
21 States including generic oxycodone, of which it is one of the largest manufacturers.
22 In July 2017 Mallinckrodt agreed to pay \$35 million to settle allegations brought
23 by the Department of Justice that it failed to detect and notify the DEA of suspicious
24 orders of controlled substances.

25 31. INSYS THERAPEUTICS, INC. is a Delaware corporation with its
26 principal place of business in Chandler, Arizona. Insys’s principal product and
27 source of revenue is Subsys.
28

1 32. Insys made thousands of payments to physicians nationwide, including
2 in the State, ostensibly for activities including participating on speakers' bureaus,
3 providing consulting services, assisting in post-marketing safety surveillance and
4 other services, but in fact to deceptively promote and maximize the use of opioids.

5 33. Subsys is a transmucosal immediate-release formulation (TIRF) of
6 fentanyl, contained in a single-dose spray device intended for oral, under the tongue
7 administration. Subsys was approved by the FDA solely for the treatment of
8 breakthrough cancer pain.

9 34. In 2016, Insys made approximately \$330 million in net revenue from
10 Subsys. Insys promotes, sells, and distributes Subsys throughout the United States,
11 the County, and Plaintiffs' Community.

12 35. Insys's founder and owner was recently arrested and charged, along
13 with other Insys executives, with multiple felonies in connection with an alleged
14 conspiracy to bribe practitioners to prescribe Subsys and defraud insurance
15 companies. Other Insys executives and managers were previously indicted.

16 **2. Distributor Defendants.**

17 36. The Distributor Defendants also are defined below. At all relevant
18 times, the Distributor Defendants have distributed, supplied, sold, and placed into
19 the stream of commerce the prescription opioids, without fulfilling the fundamental
20 duty of wholesale drug distributors to detect and warn of diversion of dangerous
21 drugs for non-medical purposes. The Distributor Defendants universally failed to
22 comply with federal and/or state law. The Distributor Defendants are engaged in
23 "wholesale distribution," as defined under state and federal law. Plaintiffs allege the
24 unlawful conduct by the Distributor Defendants is responsible for the volume of
25 prescription opioids plaguing Plaintiffs' Community.

26 37. McKESSON CORPORATION ("McKesson") at all relevant times,
27 operated as a licensed distributor in California, licensed by the California State
28 Board of Pharmacy and holding both wholesaler and out of state wholesaler

1 distributor licenses. McKesson is a Delaware corporation. McKesson has its
2 principal place of business located in San Francisco, California. McKesson operates
3 distribution centers in Chino, Fullerton, Sacramento and Visalia, California.

4 38. CARDINAL HEALTH, INC. (“Cardinal”) at all relevant times,
5 operated as a licensed distributor in California, licensed by the California State
6 Board of Pharmacy and holding both wholesaler and out of state wholesaler
7 distributor licenses. Cardinal’s principal office is located in Dublin, Ohio. Cardinal
8 operates a distribution center in Sacramento, California.

9 39. AMERISOURCEBERGEN DRUG CORPORATION
10 (“AmerisourceBergen”) at all relevant times, operated as a licensed distributor in
11 California, licensed by the California State Board of Pharmacy and holding both
12 wholesaler and out of state wholesaler distributor licenses. AmerisourceBergen is a
13 Delaware corporation and its principal place of business is located in Chesterbrook,
14 Pennsylvania.

15 40. Defendant CVS HEALTH CORPORATION is a Delaware
16 corporation with its principal place of business in Rhode Island. CVS Health
17 Corporation conducts business as a licensed wholesale distributor under the
18 following named business entities: CVS Indiana, L.L.C.; CVS Orlando FL
19 Distribution; CVS Pharmacy, Inc.; CVS RX Services, Inc, d/b/a CVS Pharmacy
20 Distribution Center; CVS TN Distribution, LLC ; and CVS VERO FL Distribution,
21 L.L.C (collectively “CVS”). At all times relevant to this Complaint, CVS
22 distributed prescription opioids throughout the United States, including in the State
23 and the County and Plaintiffs’ Community specifically. At all relevant times, this
24 Defendant operated as a licensed distributor in California, licensed by the California
25 State Board of Pharmacy.

26 41. Defendant THE KROGER CO. is an Ohio corporation with
27 headquarters in Cincinnati, OH. Kroger operates 2,268 pharmacies in the United
28 States, including in California. The Kroger Co. conducts business as a licensed

1 wholesale distributor under the following named business entities: Kroger Limited
 2 Partnership I and Kroger Limited Partnership II (collectively “Kroger”). At all
 3 times relevant to this Complaint, Kroger distributed and dispensed prescription
 4 opioids throughout the United States, including in California and Plaintiffs’
 5 Community specifically. At all relevant times, this Defendant operated licensed
 6 pharmacies in California, licensed by the California State Board of Pharmacy.

7 42. Defendant RITE AID OF MARYLAND, INC., d/b/a Rite Aid Mid-
 8 Atlantic Customer Support Center, Inc. is a Maryland corporation with its principal
 9 office located in Camp Hill, Pennsylvania and is a subsidiary of Rite Aid
 10 Corporation. Defendant THRIFTY PAYLESS, INC. is a California corporation
 11 with its principal office in located in Camp Hill, Pennsylvania and is a subsidiary
 12 of Rite Aid Corporation. Rite Aid of Maryland, Inc., d/b/a as Rite Aid Mid-Atlantic
 13 Customer Support Center, Inc. and Thrifty Payless, Inc. are referred to as “Rite
 14 Aid.” At all times relevant to this Complaint, Rite Aid distributed prescription
 15 opioids throughout the United States, including in the State, the County and
 16 Plaintiffs’ Community specifically. Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-
 17 Atlantic Customer Support Center, Inc. conducts business as a licensed wholesale
 18 distributor under the name Rite Aid Mid-Atlantic Customer Support Center and at
 19 all relevant times, operated as a licensed distributor in California, licensed by the
 20 California State of Pharmacy. Thrifty Payless, Inc. conducts business as a licensed
 21 wholesale distributor and at all relevant times, operated as a licensed distributor in
 22 California, licensed by the California State of Pharmacy.

23 43. Defendant WALGREENS BOOTS ALLIANCE, INC., also known as
 24 Walgreen Co. (“Walgreens”) is a Delaware corporation with its principal place of
 25 business in Illinois. Walgreens Boots Alliance Inc. conducts business as a licensed
 26 wholesale distributor under the following named business entities: Walgreen Co.;
 27 Walgreen Eastern Co., Inc.; Walgreen Arizona Drug Co. (collectively
 28 “Walgreens”). At all times relevant to this Complaint, Walgreens distributed

1 prescription opioids throughout the United States, including in the State, the County
2 and Plaintiffs' Community specifically. At all relevant times, this Defendant
3 operated as a licensed distributor in California, licensed by the California State
4 Board of Pharmacy.

5 44. Defendant WAL-MART INC., formerly known as Wal-Mart Stores,
6 Inc. ("Wal-Mart"), is a Delaware corporation with its principal place of business in
7 Arkansas. At all times relevant to this Complaint, Wal-Mart distributed prescription
8 opioids throughout the United States, including in the State, the County and
9 Plaintiffs' Community specifically. Wal-Mart Stores, Inc. conducts business as a
10 licensed wholesale distributor under the following named business entities: Wal-
11 Mart Warehouse #28; Wal-Mart Warehouse #6045 aka Wal-Mart Warehouse #45;
12 Wal-Mart Warehouse # 6046 aka Wal-Mart Warehouse #46 ("collectively "Wal-
13 Mart"). At all relevant times, this Defendant operated as a licensed distributor in
14 California, licensed by the California State Board of Pharmacy.

15 45. Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, Wal-
16 Mart are referred to as "National Retail Pharmacies." Cardinal, McKesson,
17 AmerisourceBergen, and the National Retail Pharmacies are collectively referred
18 to as the "Distributor Defendants."

19 46. Defendants include the above referenced entities as well as their
20 predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the
21 extent that they are engaged in the manufacture, promotion, distribution, sale and/or
22 dispensing of opioids.

23 **III. JURISDICTION & VENUE**

24 47. This Court has subject matter jurisdiction under 28 U.S.C. § 1331
25 based upon the federal claims asserted under the Racketeer Influenced and Corrupt
26 Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has
27 supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. §
28

1 1367 because those claims are so related to Plaintiffs' federal claims that they form
2 part of the same case or controversy.

3 48. This Court has personal jurisdiction over Defendants because they
4 conduct business in the State, purposefully direct or directed their actions toward
5 the State, some or all consented to be sued in the State by registering an agent for
6 service of process, they consensually submitted to the jurisdiction of the State when
7 obtaining a manufacturer or distributor license, and because they have the requisite
8 minimum contacts with the State necessary to constitutionally permit the Court to
9 exercise jurisdiction.

10 49. This Court also has personal jurisdiction over all of the defendants
11 under 18 U.S.C. § 1965(b). This Court may exercise nation-wide jurisdiction over
12 the named Defendants where the "ends of justice" require national service and
13 Plaintiffs demonstrate national contacts. Here, the interests of justice require that
14 Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before
15 the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance*
16 *Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796, 803 (N.D. Ohio 1998) (citing
17 *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *2 (N.D. Ill.
18 Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535,
19 539 (9th Cir. 1986)).

20 50. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18
21 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the
22 claim occurred in this District and each Defendant transacted affairs and conducted
23 activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); 18
24 U.S.C. §1965(a).

1 **IV. FACTUAL BACKGROUND**

2 **A. THE OPIOID EPIDEMIC.**

3 **1. The National Opioid Epidemic.**

4 51. The past two decades have been characterized by increasing abuse and
5 diversion of prescription drugs, including opioid medications, in the United States.⁹

6 52. Prescription opioids have become widely prescribed. By 2010, enough
7 prescription opioids were sold to medicate every adult in the United States with a
8 dose of 5 milligrams of hydrocodone every 4 hours for 1 month.¹⁰

9 53. By 2011, the U.S. Department of Health and Human Resources,
10 Centers for Disease Control and Prevention, declared prescription painkiller
11 overdoses at epidemic levels. The News Release noted:

- 12 a. The death toll from overdoses of prescription painkillers has more than
13 tripled in the past decade.
- 14 b. More than 40 people die every day from overdoses involving narcotic
15 pain relievers like hydrocodone (Vicodin), methadone, oxycodone
(OxyContin), and oxymorphone (Opana).
- 16 c. Overdoses involving prescription painkillers are at epidemic levels and
17 now kill more Americans than heroin and cocaine combined.
- 18 d. The increased use of prescription painkillers for nonmedical reasons,
19 along with growing sales, has contributed to a large number of
20 overdoses and deaths. In 2010, 1 in every 20 people in the United
21 States age 12 and older—a total of 12 million people—reported using
22 prescription painkillers non-medically according to the National
23 Survey on Drug Use and Health. Based on the data from the Drug
24 Enforcement Administration, sales of these drugs to pharmacies and
25 health care providers have increased by more than 300 percent since
1999.
- 26 e. Prescription drug abuse is a silent epidemic that is stealing thousands
27 of lives and tearing apart communities and families across America.

26 ⁹ See Richard C. Dart et al., Trends in Opioid Analgesic Abuse and Mortality in the
27 United States, 372 N. Eng. J. Med. 241 (2015).

28 ¹⁰ Katherine M. Keyes et al., Understanding the Rural-Urban Differences in
Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J.
Pub. Health e52 (2014).

1 f. Almost 5,500 people start to misuse prescription painkillers every
2 day.¹¹

3 54. The number of annual opioid prescriptions written in the United States
4 is now roughly equal to the number of adults in the population.¹²

5 55. Many Americans are now addicted to prescription opioids, and the
6 number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug
7 overdoses killed roughly 64,000 people in the United States, an increase of more
8 than 22 percent over the 52,404 drug deaths recorded the previous year.¹³

9 56. Moreover, the CDC has identified addiction to prescription pain
10 medication as the strongest risk factor for heroin addiction. People who are addicted
11 to prescription opioid painkillers are forty times more likely to be addicted to
12 heroin.¹⁴

13 57. Heroin is pharmacologically similar to prescription opioids. The
14 majority of current heroin users report having used prescription opioids non-
15 medically before they initiated heroin use. Available data indicates that the
16 nonmedical use of prescription opioids is a strong risk factor for heroin use.¹⁵

17 58. The CDC reports that drug overdose deaths involving heroin continued
18 to climb sharply, with heroin overdoses more than tripling in 4 years. This increase
19 mirrors large increases in heroin use across the country and has been shown to be

20 ¹¹ See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of
21 Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels
22 (Nov. 1, 2011),
23 https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

24 ¹² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*,
25 374 N. Eng. J. Med. 1480 (2016).

26 ¹³ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human
27 Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016),
28 https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

¹⁴ See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human
Servs., *Today's Heroin Epidemic*,
<https://www.cdc.gov/vitalsigns/heroin/index.html> (last updated July 7, 2015).

¹⁵ See Wilson M. Compton, Relationship Between Nonmedical Prescription-
Opioid Use and Heroin, 374 N. Eng. J. Med. 154 (2016).

1 closely tied to opioid pain reliever misuse and dependence. *Past misuse of*
 2 *prescription opioids is the strongest risk factor for heroin initiation and use,*
 3 specifically among persons who report past-year dependence or abuse. The
 4 increased availability of heroin, combined with its relatively low price (compared
 5 with diverted prescription opioids) and high purity appear to be major drivers of the
 6 upward trend in heroin use and overdose.¹⁶

7 59. The societal costs of prescription drug abuse are “huge.”¹⁷

8 60. Across the nation, local governments are struggling with a pernicious,
 9 ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90
 10 Americans lose their lives after overdosing on opioids.¹⁸

11 61. The National Institute on Drug Abuse identifies misuse and addiction
 12 to opioids as “a serious national crisis that affects public health as well as social and
 13 economic welfare.”¹⁹ The economic burden of prescription opioid misuse alone is
 14 \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction
 15 treatment, and criminal justice expenditures.²⁰

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20 ¹⁶ See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—*
United States, 2000–2014, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

21 ¹⁷ See Amicus Curiae Brief of Healthcare Distribution Management Association in
 22 Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States*
 23 *Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10
 [hereinafter Brief of HDMA].

24 ¹⁸ Opioid Crisis, NIH, National Institute on Drug Abuse (available at
 25 <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis>, last visited Sept. 19,
 26 2017) (“Opioid Crisis, NIH”) (citing at note 1 Rudd RA, Seth P, David F, Scholl L,
Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–
2015, MMWR MORB MORTAL WKLY REP. 2016;65,
 doi:10.15585/mmwr.mm65051e1).

27 ¹⁹ Opioid Crisis, NIH.

28 ²⁰ *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, *The Economic Burden*
of Prescription Opioid Overdose, Abuse, and Dependence in the United States,
2013, MED CARE 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

62. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.²¹

63. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.²²

64. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are “everywhere” and mistaken as candy.²³

65. In 2016, the President of the United States declared an opioid and heroin epidemic.²⁴

66. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.²⁵ Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience

²¹ See Rose A. Rudd et al., Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015, 65 *Morbidity & Mortality Wkly. Rep.* 1445 (2016).

²² See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 *N. Eng. J. Med.* 1253 (2016).

²³ Julie Turkewitz, ‘*The Pills are Everywhere*’: *How the Opioid Crisis Claims Its Youngest Victims*, N.Y. Times, Sept. 20, 2017 (“‘It’s a cancer,’ said [grandmother of dead one-year old], of the nation’s opioid problem, ‘with tendrils that are going everywhere.’”).

²⁴ See Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming “Prescription Opioid and Heroin Epidemic Awareness Week”).

²⁵ See Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), <https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf>.

1 hundreds of millions of dollars of injury – if not more – caused by the reasonably
2 foreseeable consequences of the prescription opioid addiction epidemic.

3 67. The prescription opioid manufacturers and distributors, including the
4 Defendants, have continued their wrongful, intentional, and unlawful conduct,
5 despite their knowledge that such conduct is causing and/or contributing to the
6 national, state, and local opioid epidemic.

7 **2. The California Opioid Epidemic.**

8 68. California has been especially ravaged by the national opioid crisis.

9 69. More people die each year from drug overdoses in California than in
10 any other state.²⁶ The State's death rate has continued to climb, increasing by 30
11 percent from 1999 to 2015, according to the Center for Disease Control (CDC).²⁷

12 70. In 2016, 1,925 Californians died due to prescription opioids.²⁸ This
13 number is on par with other recent years: in 2015, 1,966 deaths in California were
14 due just to prescription opioids (not including heroin); in 2014 that number was
15 even higher at 2,024 prescription opioid deaths; and in 2013, 1,934 Californians
16 died from a prescription opioid overdose.²⁹

22 ²⁶ Kristina Davis, "How California ranks in the nation's opioid epidemic," *The San*
23 *Diego Union-Tribune* (Nov. 8, 2017) available at
24 [http://www.sandiegouniontribune.com/news/health/sd-me-opioid-conference-](http://www.sandiegouniontribune.com/news/health/sd-me-opioid-conference-20171108-story.html)
25 [20171108-story.html](http://www.sandiegouniontribune.com/news/health/sd-me-opioid-conference-20171108-story.html) (last visited March 2, 2018).

26 ²⁷ Soumya Karlamangla, "California's opioid death rate is among the national's
27 lowest. Experts aren't sure why," *The Los Angeles Times* (Oct. 27, 2017) available
28 at [http://www.latimes.com/health/la-me-ln-california-opioids-20171026-](http://www.latimes.com/health/la-me-ln-california-opioids-20171026-htmlstory.html)
htmlstory.html (last visited March 2, 2018).

²⁸ Davis, *supra*.

²⁹ California Department of Public Health, *California Opioid Overdose*
Surveillance Dashboard, available at https://pdop.shinyapps.io/ODdash_v1/ (last
visited March 2, 2018).

1 71. Of the 1,925 opioid-related deaths in California in 2016, fentanyl was
2 a factor in at least 234 of them.³⁰ This is an increase of 47 percent for 2016.³¹
3 Heroin-related deaths have risen by 67 percent in California since 2006.³²

4 72. The high number of deaths are due in part to the extraordinary number
5 of opioids prescribed in the State. Over 23.6 million prescriptions for opioids were
6 written in California in just 2016.³³

7 73. The California Department of Public Health tracks the number of
8 reported hospitalizations and emergency department visits due to prescription
9 opioids.³⁴ In 2015, the last year for which information is currently available,
10 California had 3,935 emergency department visits and 4,095 hospitalizations
11 related to prescription opioid overdoses (excluding heroin).³⁵ The numbers were
12 even higher in 2014, when 4,106 people visited the emergency department and
13 4,482 people were hospitalized due to prescription opioid abuse.³⁶ In 2013, there
14 were 3,964 emergency department visits and 4,344 hospitalizations for prescription
15 opioid overdoses.³⁷ When emergency visits and hospitalizations include heroin, the
16 numbers are even higher.³⁸

19 ³⁰ Davis, *supra*.

20 ³¹ Karlamangla, *supra*.

21 ³² California Department of Public Health, *State of California Strategies to Address*
22 *Prescription Drug (Opioid) Misuse, Abuse, and Overdose Epidemic in California*
at 3 (June 2016), available at
23 <https://www.cdph.ca.gov/Programs/CCDCPHP/DCDIC/SACB/CDPH%20Document%20Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf> (last visited March 2, 2018).

24 ³³ California Department of Public Health, *California Opioid Overdose*
25 *Surveillance Dashboard*, *supra*.

26 ³⁴ *Id.*

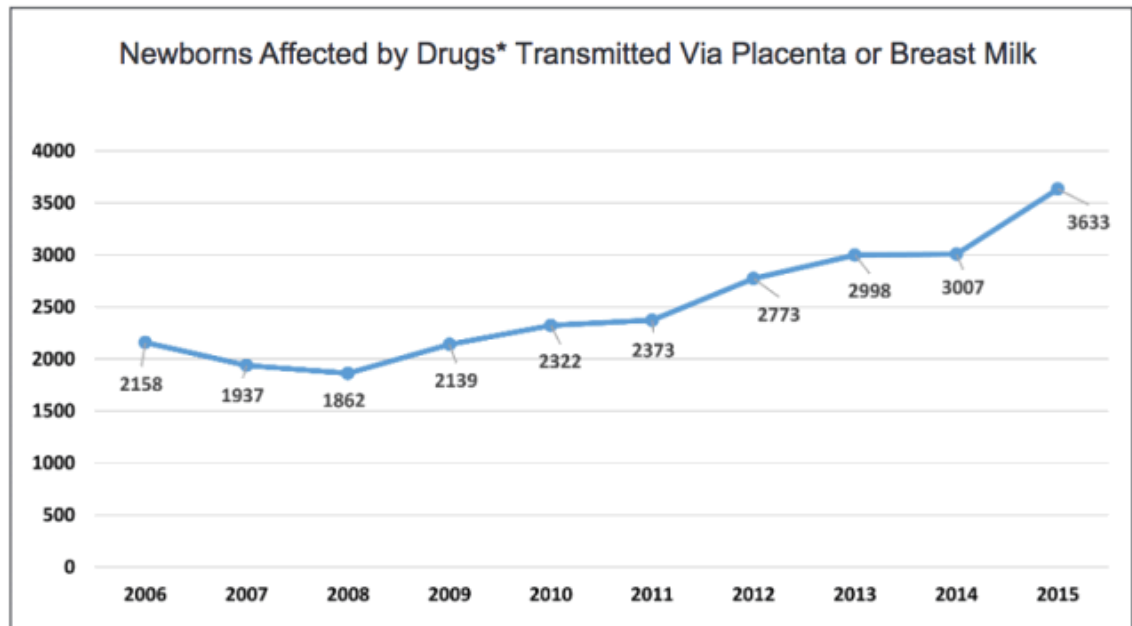
27 ³⁵ *Id.*

28 ³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

74. Neonatal Abstinence Syndrome (NAS), a collection of symptoms newborn babies experience withdrawing from opioid medications taken by the mother, has increased dramatically in California, with the rate of infants born with NAS more than tripling from 2008 to 2013.³⁹ While the number of affected newborns rose from 1,862 in 2008 to 3,007 in 2014, that number jumped by another



*Includes cocaine, hallucinogenic agents, other narcotics, other drugs of addiction, or noxious substances, or those that displayed withdrawal symptoms of the same.
Source: Inpatient Discharge Data, 2006 – 2015; Office of Statewide Health Planning and Development

21 percent in 2015.⁴⁰ This is despite a steady decline in the overall number of birth in California during that same time.⁴¹

³⁹ California Child Welfare Co-Investment Partnership, *A Matter of Substance, Challenges and Responses to Parental Substance Use in Child Welfare*, at 5 (Summer 2017), available at http://www.chhs.ca.gov/Child%20Welfare/CCW_Co-Invest_Insights_DIGITAL_FINAL_053017.pdf (last visited March 2, 2018).

⁴⁰ Cheryl Clark, "Report Shows Spike in San Diego County Babies Born with Drugs in their Systems," *KPBS* (April 17, 2017), available at <http://www.kpbs.org/news/2017/apr/17/report-shows-spike-san-diego-county-babies-born-dr/> (last visited March 2, 2018).

⁴¹ *Id.*

1 75. Reports from California's Office of Statewide Health Planning, which
2 collects data from licensed health care facilities, have shown a 95 percent increase
3 between 2008 and 2015 of newborns affected by drugs transmitted via placenta or
4 breast milk.⁴²

5 76. The opioid epidemic has also had an impact on crime in California.
6 Pharmacy robberies have gone up by 163 percent in California over the last two
7 years, according to the DEA. The DEA recorded 90 incidents in 2015, 154 in 2016
8 and, through mid-November of 2017, that number had climbed to 237.⁴³ Most
9 perpetrators were after prescription opioids.⁴⁴ In addition, fentanyl seizures at
10 California ports increased 266 percent in fiscal year 2017.⁴⁵

11 **3. The Opioid Epidemic in Plaintiffs' Community.**

12 77. The opioid epidemic is particularly devastating in Plaintiffs'
13 Community.

14 78. In 2016, the County had an opioid overdose death rate of 8.1 per
15 100,000 people.⁴⁶ In 2015, the County's opioid overdose death rate was in the
16 second highest quartile in the State.⁴⁷

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19 ⁴² California Child Welfare Co-Investment Partnership, *supra*, at 3.

20 ⁴³ Ed Fletcher, "What's behind the spike in drug store robberies?" *The Sacramento*
21 *Bee*, Dec. 8, 2017 (available at
<http://www.sacbee.com/news/local/crime/article188636384.html> (last visited
22 March 2, 2018)).

⁴⁴ *Id.*

23 ⁴⁵ United State Department of Justice, The United States Attorney's Office,
24 Southern District of California, *U.S. Attorney Appoints Opioid Coordinators* (Feb.
8, 2018) available at [https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-](https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-opioid-coordinators)
opioid-coordinators (last visited March 2, 2018).

25 ⁴⁶ California Department of Public Health, *California Opioid Overdose*
26 *Surveillance Dashboard*, available at https://pdop.shinyapps.io/ODdash_v1/ (last
visited April 20, 2018) (Yuba County specific page).

27 ⁴⁷ Public Health Institute, Tackling An Epidemic: An Assessment of the California
28 Opioid Safety Coalitions Network, at p. 11, available at
[https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27tt](https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27tt dpzxmbclj7cxq99alz.pdf)
dpzxmbclj7cxq99alz.pdf (last visited April 20, 2018).

1 79. In 2016, an estimated 5.9 percent of the population aged 12 and up in
2 Yuba County misused opioids – that’s over 4,000 people – and over one percent
3 (728 people) had an opioid use disorder.⁴⁸

4 80. From 2012 to 2014, the County suffered 22 deaths due to drug
5 overdoses for a drug overdose mortality rate of 10 deaths per 100,000 residents.⁴⁹

6 81. The CDC has tracked prescription rates per county in the United
7 States, identifying the geographic “hotspots” for rates of opioid prescriptions.⁵⁰ The
8 CDC has calculated the geographic distribution at county levels of opioid
9 prescriptions dispensed per 100 persons,⁵¹ revealing that Yuba County has been a
10 consistent hotspot over at least the past decade.

11 82. The CDC’s statistics prove that the opioid prescription rates in Yuba
12 County have exceeded any legitimate medical, scientific, or industrial purpose. The
13 overall opioid prescribing rate in 2016 was 66.5 prescriptions per 100 people
14 nationally and 44.8 in California.⁵² However, in Yuba County, California, the 2016
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21 ⁴⁸ Lisa Clemans-Cope, Marni Epstein, and Doug Wissoker, “County-Level
22 Estimates of Opioid Use Disorder and Treatment Needs in California,” *The Urban*
23 *Institute*, March 19, 2018, available at
24 <https://www.urban.org/sites/default/files/yuba.pdf> (last visited April 20, 2018).

25 ⁴⁹ County Health Rankings & Roadmaps, Drug overdose deaths, available at
26 <http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/data>
27 (last visited April 20, 2018).

28 ⁵⁰ U.S. Prescribing Rate Maps, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
2017).

⁵¹ *Id.*

⁵² *Id.* See also U.S. State Prescribing Rates, 2016, available at
<https://www.cdc.gov/drugoverdose/maps/rxstate2016.html> (last visited April 18,
2018).

1 prescription rate was 83.2 per 100 people.⁵³ This is down from the 2015 prescribing
 2 rate for Yuba County which was 92.0 per 100 people.⁵⁴

3 83. Unfortunately, the 2015 and 2016 high rates of opioid prescriptions
 4 were not an aberration for Yuba County. Consistently, the opioid prescribing rates
 5 in Yuba County have been among the highest in the state, significantly greater than
 6 the national and state averages, and often more than one prescription per person
 7 living in the County. Compared to a national average of 75.6 opioid prescriptions
 8 per 100 people in 2014⁵⁵ and 52.7 in California,⁵⁶ the Yuba County opioid
 9 prescription rate was 96.2 per 100 people.⁵⁷ In 2013, the national average was 78.1
 10 opioid prescriptions per 100 people,⁵⁸ but the opioid prescription rate in Yuba
 11 County was 105.5 per 100 people – more than one prescription for every man,
 12 woman and child in Yuba County.⁵⁹ Compared to a national average of 81.3 opioid
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16 ⁵³ U.S. County Prescribing Rates, 2016, (reporting for “Yuba, CA” here and
 17 below) CDC available at
 18 <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html> (last visited April 18,
 2018).

19 ⁵⁴ U.S. County Prescribing Rates, 2015, CDC, available at
 20 <https://www.cdc.gov/drugoverdose/maps/rxcounty2015.html> (last visited April 18,
 2018).

21 ⁵⁵ U.S. Prescribing Rate Maps, CDC, available at
 22 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

23 ⁵⁶ U.S. State Prescribing Rates, 2014, CDC, available at
 24 <https://www.cdc.gov/drugoverdose/maps/rxstate2014.html> (last visited Dec. 11,
 2017).

25 ⁵⁷ U.S. County Prescribing Rates, 2014, CDC, available at
 26 <https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html> (last visited April 18,
 2018).

27 ⁵⁸ U.S. Prescribing Rate Maps, CDC, available at
 28 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

⁵⁹ U.S. County Prescribing Rates, 2013, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxcounty2013.html> (last visited April 18,
 2018).

1 prescriptions per 100 people in 2012,⁶⁰ the opioid prescription rate in Yuba County
 2 was 108 per 100 people that year.⁶¹ In 2011, the national average was 80.9 opioid
 3 prescriptions per 100 people,⁶² but the opioid prescription rate in Yuba County was
 4 108.8 per 100 people.⁶³ Compared to a national average of 81.2 opioid prescriptions
 5 per 100 people in 2010,⁶⁴ the Yuba County opioid prescription rate was 111.2 per
 6 100 people – an all-time high for Yuba County.⁶⁵ In 2009, the national average was
 7 79.5 opioid prescriptions per 100 people,⁶⁶ but the rate in Yuba County was 98.5.⁶⁷

15 ⁶⁰ U.S. Prescribing Rate Maps, CDC, available at
 16 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

17 ⁶¹ U.S. County Prescribing Rates, 2012, CDC, available at
 18 <https://www.cdc.gov/drugoverdose/maps/rxcounty2012.html> (last visited April 18,
 2018).

19 ⁶² U.S. Prescribing Rate Maps, CDC, available at
 20 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

21 ⁶³ U.S. County Prescribing Rates, 2011, CDC, available at
 22 <https://www.cdc.gov/drugoverdose/maps/rxcounty2011.html> (last visited April 18,
 2018).

23 ⁶⁴ U.S. Prescribing Rate Maps, CDC, available at
 24 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

25 ⁶⁵ U.S. County Prescribing Rates, 2010, CDC, available at
 26 <https://www.cdc.gov/drugoverdose/maps/rxcounty2010.html> (last visited April 18,
 2018).

27 ⁶⁶ U.S. Prescribing Rate Maps, CDC, available at
 28 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

⁶⁷ U.S. County Prescribing Rates, 2009, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxcounty2009.html> (last visited April 18,
 2018).

1 Compared to a national average of 78.2 opioid prescriptions per 100 people in
2 2008⁶⁸ and 55.1 in California,⁶⁹ the Yuba County rate was 84 per 100 people.⁷⁰

3 84. The sheer volume of these dangerously addictive drugs was destined
4 to create the present crisis of addiction, abuse, and overdose deaths.

5 **B. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE,**
6 **AND UNFAIR MARKETING OF OPIOIDS.**

7 85. The opioid epidemic did not happen by accident.

8 86. Before the 1990s, generally accepted standards of medical practice
9 dictated that opioids should only be used short-term for acute pain, pain relating to
10 recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack
11 of evidence that opioids improved patients' ability to overcome pain and function,
12 coupled with evidence of greater pain complaints as patients developed tolerance to
13 opioids over time and the serious risk of addiction and other side effects, the use of
14 opioids for chronic pain was discouraged or prohibited. As a result, doctors
15 generally did not prescribe opioids for chronic pain.

16 87. Each Manufacturer Defendant has conducted, and has continued to
17 conduct, a marketing scheme designed to persuade doctors and patients that opioids
18 can and should be used for chronic pain, resulting in opioid treatment for a far
19 broader group of patients who are much more likely to become addicted and suffer
20 other adverse effects from the long-term use of opioids. In connection with this
21 scheme, each Manufacturer Defendant spent, and continues to spend, millions of
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24 ⁶⁸ U.S. Prescribing Rate Maps, CDC, available at
25 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
26 2017).

26 ⁶⁹ U.S. State Prescribing Rates, 2008, CDC, available at
27 <https://www.cdc.gov/drugoverdose/maps/rxstate2008.html> (last visited Dec. 11,
28 2017).

27 ⁷⁰ U.S. County Prescribing Rates, 2008, CDC, available at
28 <https://www.cdc.gov/drugoverdose/maps/rxcounty2008.html> (last visited April 18,
2018).

1 dollars on promotional activities and materials that falsely deny or trivialize the
2 risks of opioids while overstating the benefits of using them for chronic pain.

3 88. The Manufacturer Defendants have made false and misleading claims,
4 contrary to the language on their drugs' labels, regarding the risks of using their
5 drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted
6 the concept of "pseudoaddiction" when signs of actual addiction began appearing
7 and advocated that the signs of addiction should be treated with more opioids; (3)
8 exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed
9 that opioid dependence and withdrawal are easily managed; (5) denied the risks of
10 higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent"
11 opioid formulations to prevent abuse and addiction. The Manufacturer Defendants
12 have also falsely touted the benefits of long-term opioid use, including the supposed
13 ability of opioids to improve function and quality of life, even though there was no
14 scientifically reliable evidence to support the Manufacturer Defendants' claims.

15 89. The Manufacturer Defendants have disseminated these common
16 messages to reverse the popular and medical understanding of opioids and risks of
17 opioid use. They disseminated these messages directly, through their sales
18 representatives, in speaker groups led by physicians the Manufacturer Defendants
19 recruited for their support of their marketing messages, and through unbranded
20 marketing and industry-funded front groups.

21 90. The Manufacturer Defendants' efforts have been wildly successful.
22 Opioids are now the most prescribed class of drugs. Globally, opioid sales generated
23 \$11 billion in revenue for drug companies in 2010 alone; sales in the United States
24 have exceeded \$8 billion in revenue annually since 2009.⁷¹ In an open letter to the
25

26 ⁷¹ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune,
27 Nov. 9, 2011, [http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-](http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/)
28 [medicine/](http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/); David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, Fin. Times,
Aug. 10, 2016, [https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-](https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95)
[a121aa8abd95](https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95).

1 nation's physicians in August 2016, the then-U.S. Surgeon General expressly
 2 connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . .
 3 [m]any of [whom] were even taught – incorrectly – that opioids are not addictive
 4 when prescribed for legitimate pain."⁷² This epidemic has resulted in a flood of
 5 prescription opioids available for illicit use or sale (the supply), and a population of
 6 patients physically and psychologically dependent on them (the demand). And
 7 when those patients can no longer afford or obtain opioids from licensed
 8 dispensaries, they often turn to the street to buy prescription opioids or even non-
 9 prescription opioids, like heroin.

10 91. The Manufacturer Defendants intentionally continued their conduct,
 11 as alleged herein, with knowledge that such conduct was creating the opioid
 12 nuisance and causing the harms and damages alleged herein.

13 **1. Each Manufacturer Defendant Used Multiple Avenues to**
 14 **Disseminate Their False and Deceptive Statements about Opioids.**

15 92. The Manufacturer Defendants spread their false and deceptive
 16 statements by marketing their branded opioids directly to doctors and patients in
 17 and around the State, including in Plaintiffs' Community. Defendants also deployed
 18 seemingly unbiased and independent third parties that they controlled to spread
 19 their false and deceptive statements about the risks and benefits of opioids for the
 20 treatment of chronic pain throughout the State and Plaintiffs' Community.

21 93. The Manufacturer Defendants employed the same marketing plans and
 22 strategies and deployed the same messages in and around the State, including in
 23 Plaintiffs' Community, as they did nationwide. Across the pharmaceutical industry,
 24 "core message" development is funded and overseen on a national basis by
 25 corporate headquarters. This comprehensive approach ensures that the
 26 Manufacturer Defendants' messages are accurately and consistently delivered
 27

28 ⁷² Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016),
<http://turnthetidex.org/>.

1 across marketing channels – including detailing visits, speaker events, and
2 advertising – and in each sales territory. The Manufacturer Defendants consider this
3 high level of coordination and uniformity crucial to successfully marketing their
4 drugs.

5 94. The Manufacturer Defendants ensure marketing consistency
6 nationwide through national and regional sales representative training; national
7 training of local medical liaisons, the company employees who respond to physician
8 inquiries; centralized speaker training; single sets of visual aids, speaker slide decks
9 and sales training materials; and nationally coordinated advertising. The
10 Manufacturer Defendants’ sales representatives and physician speakers were
11 required to stick to prescribed talking points, sales messages, and slide decks, and
12 supervisors rode along with them periodically to both check on their performance
13 and compliance.

14 **a) Direct Marketing.**

15 95. The Manufacturer Defendants’ direct marketing of opioids generally
16 proceeded on two tracks. First, each Manufacturer Defendant conducted and
17 continues to conduct advertising campaigns touting the purported benefits of their
18 branded drugs. For example, upon information and belief, the Manufacturer
19 Defendants spent more than \$14 million on medical journal advertising of opioids
20 in 2011, nearly triple what they spent in 2001.

21 96. Many of the Manufacturer Defendants’ branded ads deceptively
22 portrayed the benefits of opioids for chronic pain. For example, Endo distributed
23 and made available on its website opana.com a pamphlet promoting Opana ER with
24 photographs depicting patients with physically demanding jobs like construction
25 worker, chef, and teacher, misleadingly implying that the drug would provide long-
26 term pain-relief and functional improvement. Upon information and belief, Purdue
27 also ran a series of ads, called “Pain vignettes,” for OxyContin in 2012 in medical
28 journals. These ads featured chronic pain patients and recommended OxyContin for

1 each. One ad described a “54-year-old writer with osteoarthritis of the hands” and
 2 implied that OxyContin would help the writer work more effectively.

3 97. Second, each Manufacturer Defendant promoted the use of opioids for
 4 chronic pain through “detailers” – sales representatives who visited individual
 5 doctors and medical staff in their offices – and small-group speaker programs. The
 6 Manufacturer Defendants have not corrected this misinformation. Instead, each
 7 Defendant devoted massive resources to direct sales contacts with doctors. Upon
 8 information and belief, in 2014 alone, the Manufacturer Defendants spent in excess
 9 of \$168 million on detailing branded opioids to doctors, more than twice what they
 10 spent on detailing in 2000.

11 98. The Manufacturer Defendants’ detailing to doctors is effective.
 12 Numerous studies indicate that marketing impacts prescribing habits, with face-to-
 13 face detailing having the greatest influence. Even without such studies, the
 14 Manufacturer Defendants purchase, manipulate and analyze some of the most
 15 sophisticated data available in any industry, data available from IMS Health
 16 Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by
 17 individual doctor, which in turn allows them to target, tailor, and monitor the impact
 18 of their core messages. Thus, the Manufacturer Defendants know their detailing to
 19 doctors is effective.

20 99. The Manufacturer Defendants’ detailers have been reprimanded for
 21 their deceptive promotions. In March 2010, for example, the FDA found that
 22 Actavis had been distributing promotional materials that “minimize[] the risks
 23 associated with Kadian and misleadingly suggest[] that Kadian is safer than has
 24 been demonstrated.” Those materials in particular “fail to reveal warnings
 25 regarding potentially fatal abuse of opioids, use by individuals other than the patient
 26 for whom the drug was prescribed.”⁷³

27
 28 ⁷³ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns,
 U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb.

b) Indirect Marketing.

100. The Manufacturer Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and “key opinion leaders” (“KOLs”), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”).

101. The Manufacturer Defendants deceptively marketed opioids in the State and Plaintiffs’ Community through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their “core messages” via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

102. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties

18, 2010),
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

1 that they funded, directed, and controlled to carry out and conceal their scheme to
2 deceive doctors and patients about the risks and benefits of long term opioid use for
3 chronic pain.

4 103. Defendants also identified doctors to serve, for payment, on their
5 speakers' bureaus and to attend programs with speakers and meals paid for by
6 Defendants. These speaker programs provided: (1) an incentive for doctors to
7 prescribe a particular opioid (so they might be selected to promote the drug); (2)
8 recognition and compensation for the doctors selected as speakers; and (3) an
9 opportunity to promote the drug through the speaker to his or her peers. These
10 speakers give the false impression that they are providing unbiased and medically
11 accurate presentations when they are, in fact, presenting a script prepared by
12 Defendants. On information and belief, these presentations conveyed misleading
13 information, omitted material information, and failed to correct Defendants' prior
14 misrepresentations about the risks and benefits of opioids.

15 104. Borrowing a page from Big Tobacco's playbook, the Manufacturer
16 Defendants worked through third parties they controlled by: (a) funding, assisting,
17 encouraging, and directing doctors who served as KOLS, and (b) funding, assisting,
18 directing, and encouraging seemingly neutral and credible Front Groups. The
19 Manufacturer Defendants then worked together with those KOLs and Front Groups
20 to taint the sources that doctors and patients relied on for ostensibly "neutral"
21 guidance, such as treatment guidelines, CME programs, medical conferences and
22 seminars, and scientific articles. Thus, working individually and collectively, and
23 through these Front Groups and KOLs, the Manufacturer Defendants persuaded
24 doctors and patients that what they have long known – that opioids are addictive
25 drugs, unsafe in most circumstances for long-term use – was untrue, and that the
26 compassionate treatment of pain required opioids.

27 105. In 2007, multiple States sued Purdue for engaging in unfair and
28 deceptive practices in its marketing, promotion, and sale of OxyContin. Certain

1 states settled their claims in a series of Consent Judgments that prohibited Purdue
2 from making misrepresentations in the promotion and marketing of OxyContin in
3 the future. By using indirect marketing strategies, however, Purdue intentionally
4 circumvented these restrictions. Such actions include contributing to the creation
5 of misleading publications and prescribing guidelines which lack reliable scientific
6 basis, and promoting prescribing practices which have worsened the opioid crisis.

7 106. Pro-opioid doctors are one of the most important avenues that the
8 Manufacturer Defendants use to spread their false and deceptive statements about
9 the risks and benefits of long-term opioid use. The Manufacturer Defendants know
10 that doctors rely heavily and less critically on their peers for guidance, and KOLs
11 provide the false appearance of unbiased and reliable support for chronic opioid
12 therapy. For example, the State of New York found in its settlement with Purdue
13 that the Purdue website “In the Face of Pain” failed to disclose that doctors who
14 provided testimonials on the site were paid by Purdue and concluded that Purdue’s
15 failure to disclose these financial connections potentially misled consumers
16 regarding the objectivity of the testimonials.

17 107. Defendants utilized many KOLs, including many of the same ones.

18 108. Dr. Russell Portenoy, former Chairman of the Department of Pain
19 Medicine and Palliative Care at Beth Israel Medical Center in New York, is one
20 example of a KOL whom the Manufacturer Defendants identified and promoted to
21 further their marketing campaign. Dr. Portenoy received research support,
22 consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among
23 others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was
24 instrumental in opening the door for the regular use of opioids to treat chronic pain.
25 He served on the American Pain Society (“APS”) / American Academy of Pain
26 Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to
27 treat chronic pain, first in 1996 and again in 2009. He was also a member of the
28

1 board of the American Pain Foundation (“APF”), an advocacy organization almost
2 entirely funded by the Manufacturer Defendants.

3 109. Dr. Portenoy also made frequent media appearances promoting opioids
4 and spreading misrepresentations, such as his claim that “the likelihood that the
5 treatment of pain using an opioid drug which is prescribed by a doctor will lead to
6 addiction is extremely low.” He appeared on Good Morning America in 2010 to
7 discuss the use of opioids long-term to treat chronic pain. On this widely-watched
8 program, broadcast across the country, Dr. Portenoy claimed: “Addiction, when
9 treating pain, is distinctly uncommon. If a person does not have a history, a personal
10 history, of substance abuse, and does not have a history in the family of substance
11 abuse, and does not have a very major psychiatric disorder, most doctors can feel
12 very assured that that person is not going to become addicted.”⁷⁴

13 110. Dr. Portenoy later admitted that he “gave innumerable lectures in the
14 late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely
15 claimed that fewer than 1% of patients would become addicted to opioids.
16 According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids,
17 he and other doctors promoting them overstated their benefits and glossed over their
18 risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids
19 does not exist.”⁷⁵ Portenoy candidly stated: “Did I teach about pain management,
20 specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I
21 guess I did.”⁷⁶

22 111. Another KOL, Dr. Lynn Webster, was the co-founder and Chief
23 Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic
24

25 ⁷⁴ Good Morning America (ABC television broadcast Aug. 30, 2010).

26 ⁷⁵ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*,
27 Wall St. J., Dec. 17, 2012,
28 [https://www.wsj.com/articles/SB1000142412788732447830457817334265704460](https://www.wsj.com/articles/SB10001424127887324478304578173342657044604)
4.

⁷⁶ *Id.*

1 in Salt Lake City, Utah. Dr. Webster was President of the AAPM in 2013. He is a
2 Senior Editor of Pain Medicine, the same journal that published Endo special
3 advertising supplements touting Opana ER. Dr. Webster was the author of
4 numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr.
5 Webster was receiving significant funding from the Manufacturer Defendants
6 (including nearly \$2 million from Cephalon).

7 112. During a portion of his time as a KOL, Dr. Webster was under
8 investigation for overprescribing by the U.S. Department of Justice's Drug
9 Enforcement Agency, which raided his clinic in 2010. Although the investigation
10 was closed without charges in 2014, more than 20 of Dr. Webster's former patients
11 at the Lifetree Clinic have died of opioid overdoses.

12 113. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a
13 five question, one-minute screening tool relying on patient self-reports that
14 purportedly allows doctors to manage the risk that their patients will become
15 addicted to or abuse opioids. The claimed ability to pre-sort patients likely to
16 become addicted is an important tool in giving doctors confidence to prescribe
17 opioids long-term, and for this reason, references to screening appear in various
18 industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear
19 on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the
20 flawed science and industry bias underlying this tool, certain states and public
21 entities have incorporated the Opioid Risk Tool into their own guidelines,
22 indicating, also, their reliance on the Manufacturer Defendants and those under their
23 influence and control.

24 114. In 2011, Dr. Webster presented, via webinar, a program sponsored by
25 Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk."
26 Dr. Webster recommended use of risk screening tools, urine testing, and patient
27 agreements as a way to prevent "overuse of prescriptions" and "overdose deaths."
28

1 This webinar was available to and was intended to reach doctors in the State and
2 doctors treating members of Plaintiffs' Community.⁷⁷

3 115. Dr. Webster also was a leading proponent of the concept of
4 "pseudoaddiction," the notion that addictive behaviors should be seen not as
5 warnings, but as indications of undertreated pain. In Dr. Webster's description, the
6 only way to differentiate the two was to increase a patient's dose of opioids. As he
7 and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While*
8 *Managing Pain*—a book that is still available online—when faced with signs of
9 aberrant behavior, increasing the dose "in most cases . . . should be the clinician's
10 first response."⁷⁸ Upon information and belief, Endo distributed this book to
11 doctors. Years later, Dr. Webster reversed himself, acknowledging that
12 "[pseudoaddiction] obviously became too much of an excuse to give patients more
13 medication."⁷⁹

14 116. The Manufacturer Defendants also entered into arrangements with
15 seemingly unbiased and independent patient and professional organizations to
16 promote opioids for the treatment of chronic pain. Under the direction and control
17 of the Manufacturer Defendants, these "Front Groups" generated treatment
18 guidelines, unbranded materials, and programs that favored chronic opioid therapy.
19 They also assisted the Manufacturer Defendants by responding to negative articles,
20 by advocating against regulatory changes that would limit opioid prescribing in
21
22

23 ⁷⁷ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the*
24 *Need and the Risk*, [http://www.emergingsolutionsinpain.com/ce-education/opioid-](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_content&view=frontmatter&Itemid=303&course=209)
25 [management?option=com_content&view=frontmatter&Itemid=303&course=209](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_content&view=frontmatter&Itemid=303&course=209) (last visited Aug. 22, 2017).

26 ⁷⁸ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

27 ⁷⁹ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J.
28 *Sentinel*, Feb. 18, 2012, [http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-](http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html)
[networking-dp3p2rn-139609053.html](http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html).

1 accordance with the scientific evidence, and by conducting outreach to vulnerable
2 patient populations targeted by the Manufacturer Defendants.

3 117. These Front Groups depended on the Manufacturer Defendants for
4 funding and, in some cases, for survival. The Manufacturer Defendants also
5 exercised control over programs and materials created by these groups by
6 collaborating on, editing, and approving their content, and by funding their
7 dissemination. In doing so, the Manufacturer Defendants made sure that the Front
8 Groups would generate only the messages that the Manufacturer Defendants wanted
9 to distribute. Despite this, the Front Groups held themselves out as independent and
10 serving the needs of their members – whether patients suffering from pain or doctors
11 treating those patients.

12 118. Defendants Cephalon, Endo, Janssen, and Purdue, in particular,
13 utilized many Front Groups, including many of the same ones. Several of the most
14 prominent are described below, but there are many others, including the American
15 Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of
16 State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”),
17 the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and
18 Pain & Policy Studies Group (“PPSG”).⁸⁰

19 119. The most prominent of the Manufacturer Defendants’ Front Groups
20 was the American Pain Foundation (“APF”), which, upon information and belief,
21 received more than \$10 million in funding from opioid manufacturers from 2007
22 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued
23 education guides for patients, reporters, and policymakers that touted the benefits
24 of opioids for chronic pain and trivialized their risks, particularly the risk of
25

26 ⁸⁰ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to
27 Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015),
28 <https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>.

1 addiction. APF also launched a campaign to promote opioids for returning veterans,
2 which has contributed to high rates of addiction and other adverse outcomes –
3 including death – among returning soldiers. APF also engaged in a significant
4 multimedia campaign – through radio, television and the internet – to educate
5 patients about their “right” to pain treatment, namely opioids. All of the programs
6 and materials were available nationally and were intended to reach citizens of the
7 State and Plaintiffs’ Community.

8 120. In 2009 and 2010, more than 80% of APF’s operating budget came
9 from pharmaceutical industry sources. Including industry grants for specific
10 projects, APF received about \$2.3 million from industry sources out of total income
11 of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly
12 \$2.9 million from drug companies, out of total income of about \$3.5 million. By
13 2011, upon information and belief, APF was entirely dependent on incoming grants
14 from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

15 121. APF held itself out as an independent patient advocacy organization.
16 It often engaged in grassroots lobbying against various legislative initiatives that
17 might limit opioid prescribing, and thus the profitability of its sponsors. Upon
18 information and belief, it was often called upon to provide “patient representatives”
19 for the Manufacturer Defendants’ promotional activities, including for Purdue’s
20 Partners Against Pain and Janssen’s Let’s Talk Pain. APF functioned largely as an
21 advocate for the interests of the Manufacturer Defendants, not patients. Indeed,
22 upon information and belief, as early as 2001, Purdue told APF that the basis of a
23 grant was Purdue’s desire to “strategically align its investments in nonprofit
24 organizations that share [its] business interests.”

25 122. Plaintiffs are informed and believe that on several occasions,
26 representatives of the Manufacturer Defendants, often at informal meetings at
27 conferences, suggested activities and publications for APF to pursue. APF then
28 submitted grant proposals seeking to fund these activities and publications,

1 knowing that drug companies would support projects conceived as a result of these
2 communications.

3 123. The U.S. Senate Finance Committee began looking into APF in May
4 2012 to determine the links, financial and otherwise, between the organization and
5 the manufacturers of opioid painkillers. The investigation caused considerable
6 damage to APF's credibility as an objective and neutral third party, and the
7 Manufacturer Defendants stopped funding it. Within days of being targeted by
8 Senate investigation, APF's board voted to dissolve the organization "due to
9 irreparable economic circumstances." APF "cease[d] to exist, effective
10 immediately."⁸¹

11 124. Another front group for the Manufacturer Defendants was the
12 American Academy of Pain Medicine ("AAPM"). With the assistance, prompting,
13 involvement, and funding of the Manufacturer Defendants, the AAPM issued
14 purported treatment guidelines and sponsored and hosted medical education
15 programs essential to the Manufacturer Defendants' deceptive marketing of chronic
16 opioid therapy.

17 125. AAPM received substantial funding from opioid manufacturers. For
18 example, AAPM maintained a corporate relations council, whose members paid
19 \$25,000 per year (on top of other funding) to participate. The benefits included
20 allowing members to present educational programs at off-site dinner symposia in
21 connection with AAPM's marquee event – its annual meeting held in Palm Springs,
22 California, or other resort locations. AAPM describes the annual event as an
23 "exclusive venue" for offering education programs to doctors. Membership in the
24 corporate relations council also allows drug company executives and marketing
25

26 ⁸¹ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies'*
27 *Ties to Pain Groups*, Wash. Post, May 8, 2012,
28 https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

1 staff to meet with AAPM executive committee members in small settings.
2 Defendants Endo, Purdue, and Cephalon were members of the council and
3 presented deceptive programs to doctors who attended this annual event.

4 126. Upon information and belief, AAPM is viewed internally by Endo as
5 “industry friendly,” with Endo advisors and speakers among its active members.
6 Endo attended AAPM conferences, funded its CMEs, and distributed its
7 publications. The conferences sponsored by AAPM heavily emphasized sessions
8 on opioids – 37 out of roughly 40 at one conference alone. AAPM’s presidents have
9 included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster
10 was even elected president of AAPM while under a DEA investigation.

11 127. The Manufacturer Defendants were able to influence AAPM through
12 both their significant and regular funding and the leadership of pro-opioid KOLs
13 within the organization.

14 128. In 1996, AAPM and APS jointly issued a consensus statement, “The
15 Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat
16 chronic pain and claimed that the risk of a patients’ addiction to opioids was low.
17 Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for
18 Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement
19 remained on AAPM’s website until 2011, and, upon information and belief, was
20 taken down from AAPM’s website only after a doctor complained.⁸²

21 129. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS
22 Guidelines”) and continued to recommend the use of opioids to treat chronic pain.⁸³
23 Treatment guidelines have been relied upon by doctors, especially the general
24 practitioners and family doctors targeted by the Manufacturer Defendants.
25

26 ⁸² The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement
27 From the American Academy of Pain Medicine and the American Pain Society, 13
Clinical J. Pain 6 (1997).

28 ⁸³ Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in
Chronic Non-Cancer Pain, 10 J. Pain 113 (2009).

1 Treatment guidelines not only directly inform doctors' prescribing practices, but are
2 cited throughout the scientific literature and referenced by third-party payors in
3 determining whether they should cover treatments for specific indications.
4 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue
5 discussed treatment guidelines with doctors during individual sales visits.

6 130. At least fourteen of the 21 panel members who drafted the AAPM/APS
7 Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of
8 Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009
9 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite
10 acknowledging limited evidence, and conclude that the risk of addiction is
11 manageable for patients regardless of past abuse histories.⁸⁴ One panel member, Dr.
12 Joel Saper, Clinical Professor of Neurology at Michigan State University and
13 founder of the Michigan Headache & Neurological Institute, resigned from the
14 panel because of his concerns that the 2009 Guidelines were influenced by
15 contributions that drug companies, including Manufacturer Defendants, made to the
16 sponsoring organizations and committee members. These AAPM/APS Guidelines
17 have been a particularly effective channel of deception and have influenced not only
18 treating physicians, but also the body of scientific evidence on opioids; the
19 Guidelines have been cited hundreds of times in academic literature, were
20 disseminated in the State and/or Plaintiffs' Community during the relevant time
21 period, are still available online, and were reprinted in the Journal of Pain. The
22 Manufacturer Defendants widely referenced and promoted the 2009 Guidelines
23 without disclosing the lack of evidence to support them or the Manufacturer
24 Defendants' financial support to members of the panel.

25 131. The Manufacturer Defendants worked together, through Front Groups,
26 to spread their deceptive messages about the risks and benefits of long-term opioid
27

28 ⁸⁴ *Id.*

1 therapy. For example, Defendants combined their efforts through the Pain Care
 2 Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised of
 3 representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and
 4 Purdue) and various Front Groups, almost all of which received substantial funding
 5 from the Manufacturer Defendants. Among other projects, PCF worked to ensure
 6 that an FDA-mandated education project on opioids was not unacceptably negative
 7 and did not require mandatory participation by prescribers, which the Manufacturer
 8 Defendants determined would reduce prescribing.

9 **2. The Manufacturer Defendants’ Marketing Scheme**

10 **Misrepresented the Risks and Benefits of Opioids.**

11 **i. The Manufacturer Defendants embarked upon a campaign** 12 **of false, deceptive, and unfair assurances grossly** 13 **understating and misstating the dangerous addiction risks** 14 **of the opioid drugs.**

15 132. To falsely assure physicians and patients that opioids are safe, the
 16 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of
 17 long-term opioid use, particularly the risk of addiction, through a series of
 18 misrepresentations that have been conclusively debunked by the FDA and CDC.
 19 These misrepresentations – which are described below – reinforced each other and
 20 created the dangerously misleading impression that: (1) starting patients on opioids
 21 was low risk because most patients would not become addicted, and because those
 22 at greatest risk for addiction could be identified and managed; (2) patients who
 23 displayed signs of addiction probably were not addicted and, in any event, could
 24 easily be weaned from the drugs; (3) the use of higher opioid doses, which many
 25 patients need to sustain pain relief as they develop tolerance to the drugs, do not
 26 pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose
 27 and are inherently less addictive. The Manufacturer Defendants have not only failed
 28 to correct these misrepresentations, they continue to make them today.

133. Opioid manufacturers, including Defendants Endo Pharmaceuticals,
 Inc. and Purdue Pharma L.P., have entered into settlement agreements with public

1 entities that prohibit them from making many of the misrepresentations identified
 2 in this Complaint. Yet even afterward, each Manufacturer Defendant continued to
 3 misrepresent the risks and benefits of long-term opioid use in the State and
 4 Plaintiffs' Community and each continues to fail to correct its past
 5 misrepresentations.

6 134. Some illustrative examples of the Manufacturer Defendants' false,
 7 deceptive, and unfair claims about the purportedly low risk of addiction include:

- 8 a. Actavis's predecessor caused a patient education brochure, *Managing*
 9 *Chronic Back Pain*, to be distributed beginning in 2003 that admitted
 10 that opioid addiction is possible, but falsely claimed that it is "less
 11 likely if you have never had an addiction problem." Based on Actavis's
 acquisition of its predecessor's marketing materials along with the
 rights to Kadian, it appears that Actavis continued to use this brochure
 in 2009 and beyond.
- 12 b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide*
 13 *for People Living with Pain* (2007), which suggested that addiction is
 14 rare and limited to extreme cases of unauthorized dose escalations,
 obtaining duplicative opioid prescriptions from multiple sources, or
 theft. This publication is still available online.⁸⁵
- 15 c. Endo sponsored a website, "PainKnowledge," which, upon
 16 information and belief, claimed in 2009 that "[p]eople who take
 17 opioids as prescribed usually do not become addicted." Upon
 18 information and belief, another Endo website, PainAction.com, stated
 19 "Did you know? Most chronic pain patients do not become addicted to
 20 the opioid medications that are prescribed for them." Endo also
 distributed an "Informed Consent" document on PainAction.com that
 21 misleadingly suggested that only people who "have problems with
 22 substance abuse and addiction" are likely to become addicted to opioid
 medications.
- 23 d. Upon information and belief, Endo distributed a pamphlet with the
 24 Endo logo entitled *Living with Someone with Chronic Pain*, which
 25 stated that: "Most health care providers who treat people with pain
 agree that most people do not develop an addiction problem."
- 26 e. Janssen reviewed, edited, approved, and distributed a patient education
 guide entitled *Finding Relief: Pain Management for Older Adults*
 (2009), which described as "myth" the claim that opioids are addictive,
 and asserted as fact that "[m]any studies show that opioids are rarely
 27 addictive when used properly for the management of chronic pain."

28 ⁸⁵ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007)
 [hereinafter APF, *Treatment Options*],
<https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

- f. Janssen currently runs a website, Prescriberresponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “[m]isconceptions about opioid addiction.”⁸⁶
- h. In 2010, Mallinckrodt sponsored an initiative “Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book “Defeat Chronic Pain Now!” aimed at chronic pain patients. The book, which is still available for sale in New Mexico and elsewhere, and is promoted online at www.defeatchronicpainnow.com, advises laypeople who are considering taking opioid drugs that “[o]nly rarely does opioid medication cause a true addiction.”⁸⁷ Further, the book advises that even the issue of tolerance is “overblown,” because “[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance.” In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that “[i]t is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”
- i. Consistent with the Manufacturer Defendants’ published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon in the State and Plaintiffs’ Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.
- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “patients rarely become addicted to prescribed opioids,” citing research by their KOL, Dr. Portenoy.⁸⁸

135. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the “2016 CDC Guideline”) explains that there is “[e]xtensive evidence” of the “possible harms of opioids

⁸⁶ Am. Pain Found., *A Policymaker’s Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker’s Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>.

⁸⁷ Charles E. Argoff & Bradley S. Galer, *Defeat Chronic Pain Now!* (2010).

⁸⁸ Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

(including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .).”⁸⁹ The 2016 CDC Guideline further explains that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”⁹⁰

136. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting (“ER/LA”) opioids in 2013 and for immediate release (“IR”) opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed.⁹¹

137. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in

⁸⁹ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

⁹⁰ *Id.* at 2, 25.

⁹¹ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf>; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf>.

1 specialty and primary care outpatient centers meeting the clinical criteria for an
 2 opioid use disorder.”⁹² Endo had claimed on its www.opana.com website that
 3 “[m]ost healthcare providers who treat patients with pain agree that patients treated
 4 with prolonged opioid medicines usually do not become addicted,” but the State of
 5 New York found that Endo had no evidence for that statement. Consistent with this,
 6 Endo agreed not to “make statements that . . . opioids generally are non-addictive”
 7 or “that most patients who take opioids do not become addicted” in New York.
 8 Endo remains free, however, to make those statements in this State.

9 138. In addition to mischaracterizing the highly addictive nature of the
 10 drugs they were pushing, the Manufacturer Defendants also fostered a fundamental
 11 misunderstanding of the signs of addiction. Specifically, the Manufacturer
 12 Defendants misrepresented, to doctors and patients, that warning signs and/or
 13 symptoms of addiction were, instead, signs of undertreated pain (i.e.
 14 pseudoaddiction) – and instructed doctors to increase the opioid prescription dose
 15 for patients who were already in danger.

16 139. To this end, one of Purdue’s employees, Dr. David Haddox, invented
 17 a phenomenon called “pseudoaddiction.” KOL Dr. Portenoy popularized the term.
 18 Examples of the false, misleading, deceptive, and unfair statements regarding
 19 pseudoaddiction include:

- 20 a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing*
 21 (2007), which taught that behaviors such as “requesting drugs by
 22 name,” “demanding or manipulative behavior,” seeing more than one
 23 doctor to obtain opioids, and hoarding, are all signs of
 24 pseudoaddiction, rather than true addiction.⁹³ The 2012 edition, which
 remains available for sale online, continues to teach that
 pseudoaddiction is real.⁹⁴

25 ⁹² Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo*
 26 *Pharm. Inc.* (Assurance No. 15-228), at 16,
https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

27 ⁹³ Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide*
 (2007) at 62.

28 ⁹⁴ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s*
Guide (2d ed. 2012).

- b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.
- f. In 2010, Mallinckrodt sponsored an initiative "Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book, which is still available for sale, and is promoted online at www.defeatchronicpainnow.com, teaches laypeople that "pseudoaddiction" is "caused by their doctor not appropriately prescribing the opioid medication." It teaches that "[p]seudoaddiction happens when a patient's opioid medication is not being prescribed in doses strong enough to provide good pain relief, or if the drug is not being prescribed often enough throughout the day. . . . When a pseudoaddicted patient is prescribed the proper amount of opioid medication, he or she doesn't take any extra pills because his or her pain is relieved."

140. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

141. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening

1 tools, patient contracts, urine drug screens, and similar strategies allow them to
 2 reliably identify and safely prescribe opioids to patients predisposed to addiction.
 3 These misrepresentations were especially insidious because the Manufacturer
 4 Defendants aimed them at general practitioners and family doctors who lack the
 5 time and expertise to closely manage higher-risk patients on opioids. The
 6 Manufacturer Defendants' misrepresentations made these doctors feel more
 7 comfortable prescribing opioids to their patients, and patients more comfortable
 8 starting on opioid therapy for chronic pain. Illustrative examples include:

- 9 a. Endo paid for a 2007 supplement in the *Journal of Family Practice*
 10 written by a doctor who became a member of Endo's speakers bureau
 11 in 2010. The supplement, entitled *Pain Management Dilemmas in*
 12 *Primary Care: Use of Opioids*, emphasized the effectiveness of
 screening tools, claiming that patients at high risk of addiction could
 safely receive chronic opioid therapy using a "maximally structured
 approach" involving toxicology screens and pill counts.
- 13 b. Purdue, upon information and belief, sponsored a 2011 webinar,
 14 *Managing Patient's Opioid Use: Balancing the Need and Risk*, which
 15 claimed that screening tools, urine tests, and patient agreements
 prevent "overuse of prescriptions" and "overdose deaths."
- 16 c. As recently as 2015, upon information and belief, Purdue has
 17 represented in scientific conferences that "bad apple" patients – and
 18 not opioids – are the source of the addiction crisis and that once those
 "bad apples" are identified, doctors can safely prescribe opioids
 without causing addiction.

19 142. The 2016 CDC Guideline confirms the falsity of these claims. The
 20 Guideline explains that there are no studies assessing the effectiveness of risk
 21 mitigation strategies "for improving outcomes related to overdose, addiction, abuse
 22 or misuse."⁹⁵

23 143. A fourth category of deceptive messaging regarding dangerous opioids
 24 is the Manufacturer Defendants' false assurances regarding the alleged ease of
 25 eliminating opioid dependence. The Manufacturer Defendants falsely claimed that
 26 opioid dependence can easily be addressed by tapering and that opioid withdrawal
 27 is not a problem, but they failed to disclose the increased difficulty of stopping

28 ⁹⁵ *Id.* at 11.

1 opioids after long-term use. In truth, the 2016 CDC Guideline explains that the
 2 symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea,
 3 sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous
 4 abortion and premature labor in pregnant women.⁹⁶

5 144. The Manufacturer Defendants nonetheless downplayed the severity of
 6 opioid detoxification. For example, upon information and belief, a CME sponsored
 7 by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal
 8 symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10
 9 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain*
 10 *& Its Management*, which claimed that "[s]ymptoms of physical dependence can
 11 often be ameliorated by gradually decreasing the dose of medication during
 12 discontinuation" without mentioning any hardships that might occur.⁹⁷ Similarly, in
 13 the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!"
 14 potential opioid users are advised that tolerance to opioids is "easily remedied," and
 15 that "[a]ll patients can be safely taken off opioid medication if the dose is slowly
 16 tapered down by their doctor."

17 145. A fifth category of false, deceptive, and unfair statements the
 18 Manufacturer Defendants made to sell more drugs is that opioid dosages could be
 19 increased indefinitely without added risk. The ability to escalate dosages was
 20 critical to Defendants' efforts to market opioids for long-term use to treat chronic
 21 pain because, absent this misrepresentation, doctors would have abandoned
 22 treatment when patients built up tolerance and lower dosages did not provide pain
 23 relief. The Manufacturer Defendants' deceptive claims include:

24
 25
 26 ⁹⁶ *Id.* at 26.

27 ⁹⁷ Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its*
 28 *Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*],
<http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>, at 32.

- a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.⁹⁸ This publication is still available online.
- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."⁹⁹
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. Upon information and belief, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.¹⁰⁰

⁹⁸ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>, at 12.

⁹⁹ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

¹⁰⁰ Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>, at 32.

- h. In 2007, Purdue sponsored a CME entitled “Overview of Management Options,” that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that Non-steroidal Anti-inflammatory Drugs (“NSAIDs”) and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, “the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,” challenging the correlation between opioid dosage and overdose.¹⁰¹
- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants’ Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.¹⁰²
- k. In the 2010 Mallinckrodt/C.A.R.E.S. publication “Defeat Chronic Pain Now!”, potential opioid users are warned about the risk of “[p]seudoaddiction [b]ecause of a [l]ow [d]ose,” and advised that this condition may be corrected through the prescription of a higher dose. Similarly, the book recommends that for chronic pain patients, the opioid dose should be “gradually increased to find the best daily dose, as is done with all the other oral drugs.” The book discusses the risks of NSAIDs and other drugs at higher doses, but not explain this risk for opioids.

146. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants’ representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.”¹⁰³ More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.”¹⁰⁴ The CDC also states that there is an increased risk “for opioid use disorder, respiratory depression, and death at higher

¹⁰¹ The College on Problems of Drug Dependence, *About the College*, <http://cpdd.org> (last visited Aug. 21, 2017).

¹⁰² Brief of APF, at 9.

¹⁰³ 2016 CDC Guideline at 22–23.

¹⁰⁴ *Id.* at 23–24.

1 dosages.”¹⁰⁵ That is why the CDC advises doctors to “avoid increasing dosage” to
 2 above 90 morphine milligram equivalents per day.¹⁰⁶

3 147. Defendants’ deceptive marketing of the so-called abuse-deterrent
 4 properties of some of their opioids has created false impressions that these opioids
 5 can cure addiction and abuse.

6 148. The Manufacturer Defendants made misleading claims about the
 7 ability of their so-called abuse-deterrent opioid formulations to deter abuse. For
 8 example, Endo’s advertisements for the 2012 reformulation of Opana ER claimed
 9 that it was designed to be crush resistant, in a way that suggested it was more
 10 difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana
 11 ER Extended-Release Tablets’ “extended-release features can be compromised,
 12 causing the medication to ‘dose dump,’ when subject to . . . forms of manipulation
 13 such as cutting, grinding, or chewing, followed by swallowing.”¹⁰⁷ Also troubling,
 14 Opana ER can be prepared for snorting using commonly available methods and
 15 “readily prepared for injection.”¹⁰⁸ The letter discussed “the troubling possibility
 16 that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse
 17 is occurring via injection.”¹⁰⁹ Endo’s own studies, which it failed to disclose,
 18 showed that Opana ER could still be ground and chewed. In June 2017, the FDA
 19 requested that Opana ER be removed from the market.

20 **ii. The Manufacturer Defendants embarked upon a**
 21 **campaign of false, deceptive, and unfair assurances**
 22 **grossly overstating the benefits of the opioid drugs.**

23 149. To convince doctors and patients that opioids should be used to treat

24 ¹⁰⁵ *Id.* at 21.

25 ¹⁰⁶ *Id.* at 16.

26 ¹⁰⁷ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and
 27 Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to
 Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

28 ¹⁰⁸ *Id.* at 6.

¹⁰⁹ *Id.* at 6 n.21.

1 chronic pain, the Manufacturer Defendants also had to persuade them that there was
 2 a significant upside to long-term opioid use. But as the CDC Guideline makes clear,
 3 “[n]o evidence shows a long-term benefit of opioids in pain and function versus no
 4 opioids for chronic pain with outcomes examined at least 1 year later (with most
 5 placebo-controlled randomized trials \leq 6 weeks in duration)” and that other
 6 treatments were more or equally beneficial and less harmful than long-term opioid
 7 use.¹¹⁰ The FDA, too, has recognized the lack of evidence to support long-term
 8 opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of
 9 long-term opioid use and falsely and misleadingly suggested that these benefits
 10 were supported by scientific evidence.

11 150. Some illustrative examples of the Manufacturer Defendants’ false
 12 claims are:

- 13 a. Upon information and belief, Actavis distributed an advertisement
 14 claiming that the use of Kadian to treat chronic pain would allow
 15 patients to return to work, relieve “stress on your body and your mental
 health,” and help patients enjoy their lives.
- 16 b. Endo distributed advertisements that claimed that the use of Opana ER
 17 for chronic pain would allow patients to perform demanding tasks like
 construction work or work as a chef and portrayed seemingly healthy,
 unimpaired subjects.
- 18 c. Janssen sponsored and edited a patient education guide entitled
 19 *Finding Relief: Pain Management for Older Adults* (2009) – which
 20 states as “a fact” that “opioids may make it easier for people to live
 normally.” The guide lists expected functional improvements from
 21 opioid use, including sleeping through the night, returning to work,
 recreation, sex, walking, and climbing stairs.
- 22 d. Janssen promoted Ultracet for everyday chronic pain and distributed
 23 posters, for display in doctors’ offices, of presumed patients in active
 professions; the caption read, “Pain doesn’t fit into their schedules.”
- 24 e. Upon information and belief, Purdue ran a series of advertisements for
 25 OxyContin in 2012 in medical journals entitled “Pain vignettes,”
 26 which were case studies featuring patients with pain conditions
 27 persisting over several months and recommending OxyContin for
 28 them. The ads implied that OxyContin improves patients’ function.

¹¹⁰ *Id.* at 15.

- f. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.
- g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."¹¹¹ This publication is still available online.
- h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."¹¹² Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."
- j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."
- k. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."¹¹³ The Policymaker's Guide was originally published in 2011.
- l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

¹¹¹ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

¹¹² E.g., NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

¹¹³ Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>, at 29.

1 151. As the FDA and other agencies have made clear for years, these claims
2 have no support in the scientific literature.

3 152. In 2010, the FDA warned Actavis, in response to its advertising of
4 Kadian described above, that “we are not aware of substantial evidence or
5 substantial clinical experience demonstrating that the magnitude of the effect of the
6 drug [Kadian] has in alleviating pain, taken together with any drug-related side
7 effects patients may experience . . . results in any overall positive impact on a
8 patient’s work, physical and mental functioning, daily activities, or enjoyment of
9 life.”¹¹⁴ And in 2008, upon information and belief, the FDA sent a warning letter to
10 an opioid manufacturer, making it clear “that [the claim that] patients who are
11 treated with the drug experience an improvement in their overall function, social
12 function, and ability to perform daily activities . . . has not been demonstrated by
13 substantial evidence or substantial clinical experience.”

14 153. The Manufacturer Defendants also falsely and misleadingly
15 emphasized or exaggerated the risks of competing medications like NSAIDs, so that
16 doctors and patients would look to opioids first for the treatment of chronic pain.
17 Once again, these misrepresentations by the Manufacturer Defendants contravene
18 pronouncements by and guidance from the FDA and CDC based on the scientific
19 evidence. Indeed, the FDA changed the labels for extended-release and long-acting
20 (“ER/LA”) opioids in 2013 and immediate-release (“IR”) opioids in 2016 to state
21 that opioids should only be used as a last resort “in patients for which alternative
22 treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC
23 Guideline states that NSAIDs, not opioids, should be the first-line treatment for
24 chronic pain, particularly arthritis and lower back pain.¹¹⁵ Purdue misleadingly
25

26 ¹¹⁴ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns,
27 U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb.
18, 2010),
28 <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

¹¹⁵ 2016 CDC Guideline at 12.

1 promoted OxyContin as being unique among opioids in providing 12 continuous
2 hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a
3 fact that Purdue has known at all times relevant to this action. Upon information
4 and belief, Purdue’s own research shows that OxyContin wears off in under six
5 hours in one quarter of patients and in under 10 hours in more than half. This is
6 because OxyContin tablets release approximately 40% of their active medicine
7 immediately, after which release tapers. This triggers a powerful initial response,
8 but provides little or no pain relief at the end of the dosing period, when less
9 medicine is released. This phenomenon is known as “end of dose” failure, and the
10 FDA found in 2008 that a “substantial proportion” of chronic pain patients taking
11 OxyContin experience it. This not only renders Purdue’s promise of 12 hours of
12 relief false and deceptive, it also makes OxyContin more dangerous because the
13 declining pain relief patients experience toward the end of each dosing period drives
14 them to take more OxyContin before the next dosing period begins, quickly
15 increasing the amount of drug they are taking and spurring growing dependence.

16 154. Purdue’s competitors were aware of this problem. For example, upon
17 information and belief, Endo ran advertisements for Opana ER referring to “real”
18 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were
19 effective for a full 12 hours. Upon information and belief, Purdue’s sales
20 representatives continue to tell doctors that OxyContin lasts a full 12 hours.

21 155. Front Groups supported by Purdue likewise echoed these
22 representations. For example, in an amicus brief submitted to the Supreme Court of
23 Ohio by the American Pain Foundation, the National Foundation for the Treatment
24 of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

25 OxyContin is particularly useful for sustained long-term pain because
26 it comes in higher, compact pills with a slow release coating.
27 OxyContin pills can work for 12 hours. This makes it easier for patients
28 to comply with dosing requirements without experiencing a roller-
coaster of pain relief followed quickly by pain renewal that can occur
with shorter acting medications. It also helps the patient sleep through
the night, which is often impossible with short-acting medications. For

1 many of those serviced by Pain Care Amici, OxyContin has been a
2 miracle medication.¹¹⁶

3 156. Cephalon deceptively marketed its opioids Actiq and Fentora for
4 chronic pain even though the FDA has expressly limited their use to the treatment
5 of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely
6 powerful fentanyl-based IR opioids. Neither is approved for or has been shown to
7 be safe or effective for chronic pain. Indeed, the FDA expressly prohibited
8 Cephalon from marketing Actiq for anything but cancer pain, and refused to
9 approve Fentora for the treatment of chronic pain because of the potential harm,
10 including the high risk of “serious and life-threatening adverse events” and abuse –
11 which are greatest in non-cancer patients. The FDA also issued a Public Health
12 Advisory in 2007 emphasizing that Fentora should only be used for cancer patients
13 who are opioid-tolerant and should not be used for any other conditions, such as
14 migraines, post-operative pain, or pain due to injury.¹¹⁷ Specifically, the FDA
15 advised that Fentora “is only approved for breakthrough cancer pain in patients who
16 are *opioid-tolerant*, meaning those patients who take a regular, daily, around-the-
17 clock narcotic pain medication.”¹¹⁸

18 157. Despite this, Cephalon conducted and continues to conduct a well-
19 funded campaign to promote Actiq and Fentora for chronic pain and other non-
20 cancer conditions for which it was not approved, appropriate, and for which it is not
21 safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs,
22 journal supplements, and detailing by its sales representatives to give doctors the

23
24 ¹¹⁶ Reply Brief of Amicus Curiae of the American Pain Foundation, The National
25 Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting
26 Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13,
27 2004), 2004 WL 1637768, at *4 (footnote omitted).

28 ¹¹⁷ See U.S. Food & Drug Admin., *Public Health Advisory: Important Information
for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007),
<https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

¹¹⁸ *Id.*

1 false impression that Actiq and Fentora are safe and effective for treating non-
2 cancer pain. For example:

- 3 a. Cephalon paid to have a CME it sponsored, *Opioid-Based*
4 *Management of Persistent and Breakthrough Pain*, published in a
5 supplement of Pain Medicine News in 2009. The CME instructed
6 doctors that “[c]linically, broad classification of pain syndromes as
7 either cancer- or non-cancer-related has limited utility” and
8 recommended Actiq and Fentora for patients with chronic pain.
- 9 b. Upon information and belief, Cephalon’s sales representatives set up
10 hundreds of speaker programs for doctors, including many non-
11 oncologists, which promoted Actiq and Fentora for the treatment of
12 non-cancer pain.
- 13 c. In December 2011, Cephalon widely disseminated a journal
14 supplement entitled “Special Report: An Integrated Risk Evaluation
15 and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and
16 Oral Transmucosal Fentanyl Citrate (ACTIQ)” to Anesthesiology
17 News, Clinical Oncology News, and Pain Medicine News – three
18 publications that are sent to thousands of anesthesiologists and other
19 medical professionals. The Special Report openly promotes Fentora
20 for “multiple causes of pain” – and not just cancer pain.

14 158. Cephalon’s deceptive marketing gave doctors and patients the false
15 impression that Actiq and Fentora were not only safe and effective for treating
16 chronic pain, but were also approved by the FDA for such uses.

17 159. Purdue also unlawfully and unfairly failed to report or address illicit
18 and unlawful prescribing of its drugs, despite knowing about it for years. Purdue’s
19 sales representatives have maintained a database since 2002 of doctors suspected of
20 inappropriately prescribing its drugs. Rather than report these doctors to state
21 medical boards or law enforcement authorities (as Purdue is legally obligated to do)
22 or cease marketing to them, Purdue used the list to demonstrate the high rate of
23 diversion of OxyContin – the same OxyContin that Purdue had promoted as less
24 addictive – in order to persuade the FDA to bar the manufacture and sale of generic
25 copies of the drug because the drug was too likely to be abused. In an interview
26 with the Los Angeles Times, Purdue’s senior compliance officer acknowledged that
27 in five years of investigating suspicious pharmacies, Purdue failed to take action –
28 even where Purdue employees personally witnessed the diversion of its drugs. The

1 same was true of prescribers; despite its knowledge of illegal prescribing, Purdue
 2 did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin
 3 tablets and that Purdue's district manager described it internally as "an organized
 4 drug ring" until years after law enforcement shut it down. In doing so, Purdue
 5 protected its own profits at the expense of public health and safety.¹¹⁹

6 160. Like Purdue, Endo has been cited for its failure to set up an effective
 7 system for identifying and reporting suspicious prescribing. In its settlement
 8 agreement with Endo, the State of New York found that Endo failed to require sales
 9 representatives to report signs of abuse, diversion, and inappropriate prescribing;
 10 paid bonuses to sales representatives for detailing prescribers who were
 11 subsequently arrested or convicted for illegal prescribing; and failed to prevent sales
 12 representatives from visiting prescribers whose suspicious conduct had caused them
 13 to be placed on a no-call list.

14 **3. The Manufacturer Defendants Targeted Susceptible Prescribers** 15 **and Vulnerable Patient Populations.**

16 161. As a part of their deceptive marketing scheme, the Manufacturer
 17 Defendants identified and targeted susceptible prescribers and vulnerable patient
 18 populations in the U.S., including this State and Plaintiffs' Community. For
 19 example, the Manufacturer Defendants focused their deceptive marketing on
 20 primary care doctors, who were more likely to treat chronic pain patients and
 21 prescribe them drugs, but were less likely to be educated about treating pain and the
 22 risks and benefits of opioids and therefore more likely to accept the Manufacturer
 23 Defendants' misrepresentations.

24 162. The Manufacturer Defendants also targeted vulnerable patient
 25 populations like the elderly and veterans, who tend to suffer from chronic pain. The
 26

27 ¹¹⁹ Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the*
 28 *Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10,
 2016, <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

1 Manufacturer Defendants targeted these vulnerable patients even though the risks
 2 of long-term opioid use were significantly greater for them. For example, the 2016
 3 CDC Guideline observes that existing evidence confirms that elderly patients taking
 4 opioids suffer from elevated fall and fracture risks, reduced renal function and
 5 medication clearance, and a smaller window between safe and unsafe dosages.¹²⁰
 6 The 2016 CDC Guideline concludes that there must be “additional caution and
 7 increased monitoring” to minimize the risks of opioid use in elderly patients. *Id.* at
 8 27. The same is true for veterans, who are more likely to use anti-anxiety drugs
 9 (benzodiazepines) for post-traumatic stress disorder, which interact dangerously
 10 with opioids.

11 **4. Insys Employed Fraudulent, Illegal, and Misleading Marketing** 12 **Schemes to Promote Subsys.**

13 163. Insys’s opioid, Subsys, was approved by the FDA in 2012 for
 14 “management of breakthrough pain in adult cancer patients who are already
 15 receiving and who are tolerant to around-the-clock opioid therapy for their
 16 underlying persistent cancer pain.” Under FDA rules, Insys could only market
 17 Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl,
 18 administered via a sublingual (under the tongue) spray, which provides rapid-onset
 19 pain relief. It is in the class of drugs described as Transmucosal Immediate-Release
 20 Fentanyl (“TIRF”).

21 164. To reduce the risk of abuse, misuse, and diversion, the FDA instituted
 22 a Risk Evaluation and Mitigation Strategy (“REMS”) for Subsys and other TIRF
 23 products, such as Cephalon’s Actiq and Fentora. The purpose of REMS was to
 24 educate “prescribers, pharmacists, and patients on the potential for misuse, abuse,
 25 addiction, and overdose” for this type of drug and to “ensure safe use and access to
 26
 27

28 ¹²⁰ 2016 CDC Guideline at 13.

1 these drugs for patients who need them.”¹²¹ Prescribers must enroll in the TIRF
2 REMS before writing a prescription for Subsys.

3 165. Since its launch, Subsys has been an extremely expensive medication,
4 and its price continues to rise each year. Depending on a patient’s dosage and
5 frequency of use, a month’s supply of Subsys could cost in the thousands of dollars.

6 166. Due to its high cost, in most instances prescribers must submit Subsys
7 prescriptions to insurance companies or health benefit payors for prior authorization
8 to determine whether they will pay for the drug prior to the patient attempting to fill
9 the prescription. According to the U.S. Senate Homeland Security and
10 Governmental Affairs Committee Minority Staff Report (“Staff Report”), the prior
11 authorization process includes “confirmation that the patient had an active cancer
12 diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was
13 being prescribed Subsys to treat breakthrough pain that the other opioid could not
14 eliminate. If any one of these factors was not present, the prior authorization would
15 be denied”¹²²

16 167. These prior authorization requirements proved to be daunting. Subsys
17 received reimbursement approval in only approximately 30% of submitted claims.
18 In order to increase approvals, Insys created a prior authorization unit, called the
19 Insys Reimbursement Center (“IRC”), to obtain approval for Subsys
20 reimbursements. This unit employed a number of fraudulent and misleading tactics
21 to secure reimbursements, including falsifying medical histories of patients, falsely
22 claiming that patients had cancer, and providing misleading information to insurers
23 and payors regarding patients’ diagnoses and medical conditions.

24
25
26 ¹²¹ Press Release, FDA, *FDA Approves Shared System REMS for TIRF Products*,
Dec. 29, 2011.

27 ¹²² U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling*
28 *an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior*
Authorization, <https://www.documentcloud.org/documents/3987564-REPORT-Fueling-an-Epidemic-Insys-Therapeutics.html>.

1 168. Subsys has proved to be extremely profitable for Insys. Insys made
2 approximately \$330 million in net revenue from Subsys last year. Between 2013
3 and 2016, the value of Insys stock rose 296%.

4 169. Since its launch in 2012, Insys aggressively worked to grow its profits
5 through fraudulent, illegal, and misleading tactics, including its reimbursement-
6 related fraud. Through its sales representatives and other marketing efforts, Insys
7 deceptively promoted Subsys as safe and appropriate for uses such as neck and back
8 pain, without disclosing the lack of approval or evidence for such uses, and
9 misrepresented the appropriateness of Subsys for treatment those conditions. It
10 implemented a kickback scheme wherein it paid prescribers for fake speakers
11 programs in exchange for prescribing Subsys. All of these fraudulent and
12 misleading schemes had the effect of pushing Insys's dangerous opioid onto
13 patients who did not need it.

14 170. Insys incentivized its sales force to engage in illegal and fraudulent
15 conduct. Many of the Insys sales representatives were new to the pharmaceutical
16 industry and their base salaries were low compared to industry standard. The
17 compensation structure was heavily weighted toward commissions and rewarded
18 reps more for selling higher (and more expensive) doses of Subsys, a "highly
19 unusual" practice because most companies consider dosing a patient-specific
20 decision that should be made by a doctor.¹²³

21 171. The Insys "speakers program" was perhaps its most widespread and
22 damaging scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam
23 action that the sole purpose of the speakers program was "in the words of his then
24 supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went
25 on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys
26 prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200
27

28 ¹²³ *Id.*

1 micrograms), would receive the invitations to the program—and the checks.”¹²⁴ It
2 was a pay-to-prescribe program.

3 172. Insys’s sham speaker program and other fraudulent and illegal tactics
4 have been outlined in great detail in indictments and guilty pleas of Insys
5 executives, employees, and prescribers across the country, as well as in a number
6 of lawsuits against the company itself.

7 173. In May of 2015, two Alabama pain specialists were arrested and
8 charged with illegal prescription drug distribution, among other charges. The
9 doctors were the top prescribers of Subsys, though neither were oncologists.
10 According to prosecutors, the doctors received illegal kickbacks from Insys for
11 prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and
12 joint pain. In February of 2016, a former Insys sales manager pled guilty to
13 conspiracy to commit health care fraud, including engaging in a kickback scheme
14 in order to induce one of these doctors to prescribe Subsys. The plea agreement
15 states that nearly all of the Subsys prescriptions written by the doctor were off-label
16 to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20
17 years in prison.

18 174. In June of 2015, a nurse practitioner in Connecticut described as the
19 state’s highest Medicare prescriber of narcotics, pled guilty to receiving \$83,000 in
20 kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed
21 the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner
22 programs at approximately \$1,000 per event; however, she did not give any
23 presentations. In her guilty plea, the nurse admitted receiving the speaker fees in
24 exchange for writing prescriptions for Subsys.

25 175. In August of 2015, Insys settled a complaint brought by the Oregon
26 Attorney General. In its complaint, the Oregon Department of Justice cited Insys
27

28 ¹²⁴ Roddy Boyd, *Insys Therapeutics and the New ‘Killing It’*, Southern
Investigative Reporting Foundation, The Investigator, April 24, 2015.

1 for, among other things, misrepresenting to doctors that Subsys could be used to
 2 treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe
 3 nor effective, and using speaking fees as kickbacks to incentivize doctors to
 4 prescribe Subsys.

5 176. In August of 2016, the State of Illinois sued Insys for similar deceptive
 6 and illegal practices. The Complaint alleged that Insys marketed Subsys to high-
 7 volume prescribers of opioid drugs instead of to oncologists whose patients
 8 experienced the breakthrough cancer pain for which the drug is indicated. The
 9 Illinois Complaint also details how Insys used its speaker program to pay high
 10 volume prescribers to prescribe Subsys. The speaker events took place at upscale
 11 restaurants in the Chicago area, and Illinois speakers received an “honorarium”
 12 ranging from \$700 to \$5,100, and they were allowed to order as much food and
 13 alcohol as they wanted. At most of the events, the “speaker” being paid by Insys
 14 did not speak, and, on many occasions, the only attendees at the events were the
 15 speaker and an Insys sales representative.

16 177. In December of 2016, six Insys executives and managers were indicted
 17 and then, in October 2017, Insys’s founder and owner was arrested and charged
 18 with multiple felonies in connection with an alleged conspiracy to bribe
 19 practitioners to prescribe Subsys and defraud insurance companies. A U.S.
 20 Department of Justice press release explained that, among other things: “Insys
 21 executives improperly influenced health care providers to prescribe a powerful
 22 opioid for patients who did not need it, and without complying with FDA
 23 requirements, thus putting patients at risk and contributing to the current opioid
 24 crisis.”¹²⁵ A Drug Enforcement Administration (“DEA”) Special Agent in Charge
 25 further explained that: “Pharmaceutical companies whose products include
 26

27 ¹²⁵ Press Release, DOJ, U.S. Attorney’s Office, Dist. of Mass., *Founder and Owner*
 28 *of Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct.
 26, 2017), available at <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

1 controlled medications that can lead to addiction and overdose have a special
2 obligation to operate in a trustworthy, transparent manner, because their customers'
3 health and safety and, indeed, very lives depend on it."¹²⁶

4 **5. The Manufacturer Defendants made Materially Deceptive**
5 **Statements and Concealed Material Facts.**

6 178. As alleged herein, the Manufacturer Defendants made and/or
7 disseminated deceptive statements regarding material facts and further concealed
8 material facts, in the course of manufacturing, marketing, and selling prescription
9 opioids. The Manufacturer Defendants' actions were intentional and/or unlawful.
10 Such statements include, but are not limited to, those set out below and alleged
11 throughout this Complaint.

12 179. Defendant Purdue made and/or disseminated deceptive statements,
13 and concealed material facts in such a way to make their statements deceptive,
14 including, but not limited to, the following:

- 15 a. Creating, sponsoring, and assisting in the distribution of patient
16 education materials distributed to consumers that contained deceptive
17 statements;
- 18 b. Creating and disseminating advertisements that contained deceptive
19 statements concerning the ability of opioids to improve function long-
20 term and concerning the evidence supporting the efficacy of opioids
21 long-term for the treatment of chronic non-cancer pain;
- 22 c. Disseminating misleading statements concealing the true risk of
23 addiction and promoting the deceptive concept of pseudoaddiction
24 through Purdue's own unbranded publications and on internet sites
25 Purdue operated that were marketed to and accessible by consumers;
- 26 d. Distributing brochures to doctors, patients, and law enforcement
27 officials that included deceptive statements concerning the indicators
28 of possible opioid abuse;
- 29 e. Sponsoring, directly distributing, and assisting in the distribution of
30 publications that promoted the deceptive concept of pseudoaddiction,
31 even for high-risk patients;

¹²⁶ *Id.*

- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

1 180. Defendant Endo made and/or disseminated deceptive statements, and
2 concealed material facts in such a way to make their statements deceptive,
3 including, but not limited to, the following:

- 4 a. Creating, sponsoring, and assisting in the distribution of patient
5 education materials that contained deceptive statements;
- 6 b. Creating and disseminating advertisements that contained deceptive
7 statements concerning the ability of opioids to improve function long-
8 term and concerning the evidence supporting the efficacy of opioids
9 long-term for the treatment of chronic non-cancer pain;
- 10 c. Creating and disseminating paid advertisement supplements in
11 academic journals promoting chronic opioid therapy as safe and
12 effective for long term use for high risk patients;
- 13 d. Creating and disseminating advertisements that falsely and
14 inaccurately conveyed the impression that Endo's opioids would
15 provide a reduction in oral, intranasal, or intravenous abuse;
- 16 e. Disseminating misleading statements concealing the true risk of
17 addiction and promoting the misleading concept of pseudoaddiction
18 through Endo's own unbranded publications and on internet sites Endo
19 sponsored or operated;
- 20 f. Endorsing, directly distributing, and assisting in the distribution of
21 publications that presented an unbalanced treatment of the long-term
22 and dose-dependent risks of opioids versus NSAIDs;
- 23 g. Providing significant financial support to pro-opioid KOLs, who made
24 deceptive statements concerning the use of opioids to treat chronic
25 non-cancer pain;
- 26 h. Providing needed financial support to pro-opioid pain organizations –
27 including over \$5 million to the organization responsible for many of
28 the most egregious misrepresentations – that made deceptive
statements, including in patient education materials, concerning the
use of opioids to treat chronic non-cancer pain;
- i. Targeting the elderly by assisting in the distribution of guidelines that
contained deceptive statements concerning the use of opioids to treat
chronic non-cancer pain and misrepresented the risks of opioid
addiction in this population;
- j. Endorsing and assisting in the distribution of CMEs containing
deceptive statements concerning the use of opioids to treat chronic
non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively
concluded opioids are safe and effective for the long-term treatment of
chronic non-cancer pain and that opioids improve quality of life, while
concealing contrary data;

1. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

181. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

182. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

183. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

6. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

184. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are

1 responsible for a long list of very serious adverse outcomes. The FDA warned
2 Defendants of this, and Defendants had access to scientific studies, detailed
3 prescription data, and reports of adverse events, including reports of addiction,
4 hospitalization, and death – all of which clearly described the harm from long-term
5 opioid use and that patients were suffering from addiction, overdose, and death in
6 alarming numbers. More recently, the FDA and CDC have issued pronouncements,
7 based on medical evidence, that conclusively expose the falsity of Defendants’
8 misrepresentations, and Endo and Purdue have recently entered into agreements in
9 New York prohibiting them from making some of the same misrepresentations
10 described in this Complaint.

11 185. At all times relevant to this Complaint, the Manufacturer Defendants
12 took steps to avoid detection of and to fraudulently conceal their deceptive
13 marketing and unlawful, unfair, and fraudulent conduct. For example, the
14 Manufacturer Defendants disguised their role in the deceptive marketing of chronic
15 opioid therapy by funding and working through third parties like Front Groups and
16 KOLs. The Manufacturer Defendants purposefully hid behind the assumed
17 credibility of these individuals and organizations and relied on them to vouch for
18 the accuracy and integrity of the Manufacturer Defendants’ false and deceptive
19 statements about the risks and benefits of long-term opioid use for chronic pain.
20 Defendants also never disclosed their role in shaping, editing, and approving the
21 content of information and materials disseminated by these third parties. The
22 Manufacturer Defendants exerted considerable influence on these promotional and
23 “educational” materials in emails, correspondence, and meetings with KOLs, Front
24 Groups, and public relations companies that were not, and have not yet become,
25 public. For example, PainKnowledge.org, which is run by the NIPC, did not
26 disclose Endo’s involvement. Other Manufacturer Defendants, such as Purdue and
27 Janssen, ran similar websites that masked their own role.

28

1 186. Finally, the Manufacturer Defendants manipulated their promotional
 2 materials and the scientific literature to make it appear that these documents were
 3 accurate, truthful, and supported by objective evidence when they were not. The
 4 Manufacturer Defendants distorted the meaning or import of studies they cited and
 5 offered them as evidence for propositions the studies did not support. The
 6 Manufacturer Defendants invented “pseudoaddiction” and promoted it to an
 7 unsuspecting medical community. The Manufacturer Defendants provided the
 8 medical community with false and misleading information about ineffectual
 9 strategies to avoid or control opioid addiction. The Manufacturer Defendants
 10 recommended to the medical community that dosages be increased, without
 11 disclosing the risks. The Manufacturer Defendants spent millions of dollars over a
 12 period of years on a misinformation campaign aimed at highlighting opioids’
 13 alleged benefits, disguising the risks, and promoting sales. The lack of support for
 14 the Manufacturer Defendants’ deceptive messages was not apparent to medical
 15 professionals who relied upon them in making treatment decisions, nor could it have
 16 been detected by the Plaintiffs or Plaintiffs’ Community. Thus, the Manufacturer
 17 Defendants successfully concealed from the medical community, patients, and
 18 health care payors facts sufficient to arouse suspicion of the claims that the Plaintiffs
 19 now assert. Plaintiffs did not know of the existence or scope of the Manufacturer
 20 Defendants’ industry-wide fraud and could not have acquired such knowledge
 21 earlier through the exercise of reasonable diligence.

22 **C. THE DISTRIBUTOR DEFENDANTS’ UNLAWFUL DISTRIBUTION**
 23 **OF OPIOIDS.**

24 187. The Distributor Defendants owe a duty under both federal law (21
 25 U.S.C. § 823, 21 CFR 1301.74) and California law (*see, e.g.*, Cal. Bus. & Prof.
 26 Code § 4169.1) to monitor, detect, investigate, refuse to fill, and report suspicious
 27 orders of prescription opioids originating from Plaintiffs’ Community as well as
 28

1 those orders which the Distributor Defendants knew or should have known were
2 likely to be diverted into Plaintiffs' Community.

3 188. The foreseeable harm from a breach of these duties is the diversion of
4 prescription opioids for nonmedical purposes.

5 189. Each Distributor Defendant repeatedly and purposefully breached its
6 duties under state and federal law. Such breaches are a direct and proximate cause
7 of the widespread diversion of prescription opioids for nonmedical purposes into
8 Plaintiffs' Community.

9 190. The unlawful diversion of prescription opioids is a direct and
10 proximate cause and/or substantial contributing factor to the opioid epidemic,
11 prescription opioid abuse, addiction, morbidity and mortality in the State and in
12 Plaintiffs' Community. This diversion and the epidemic are direct causes of harms
13 for which Plaintiffs seek to recover here.

14 191. The opioid epidemic in the State, including *inter alia* in Plaintiffs'
15 Community, remains an immediate ***hazard to public health and safety***.

16 192. The opioid epidemic in Plaintiffs' Community is a temporary and
17 continuous ***public nuisance*** and remains unabated.

18 193. The Distributor Defendants intentionally continued their conduct, as
19 alleged herein, with knowledge that such conduct was creating the opioid nuisance
20 and causing the harms and damages alleged herein.

21 **1. Wholesale Drug Distributors Have a Duty under State and**
22 **Federal Law to Guard Against, and Report, Unlawful Diversion**
23 **and to Report and Prevent Suspicious Orders.**

24 194. As under federal law, opioids are a Schedule II controlled substance
25 under California law. *See* Cal. Health & Safety Code § 11055. Opioids are
26 categorized as "Schedule II" drugs because they have a "high potential for abuse"
27 and the potential to cause "severe psychic or physical dependence" and/or "severe
28 psychological . . . dependence." 21 U.S.C. § 812(b)(2)(A)-(C).

1 195. California law required Distributor Defendants to be licensed by the
2 California State Board of Pharmacy. Cal. Bus. & Prof. Code § 4160; Cal. Bus. &
3 Prof. Code § 4161. California law required Manufacturer Defendants to be licensed
4 by the State Department of Health Services. Cal. Health & Safety Code § 111615.

5 196. The California State Board of Pharmacy has the authority to “deny,
6 revoke, or suspend any license” issued to out-of-state manufacturers or wholesale
7 distributors who violate the Pharmacy Law or the state’s Sherman Food, Drug and
8 Cosmetic Law. Cal. Bus. & Prof. Code § 4304.

9 197. It is unlawful under California law for a distributor or manufacturer to
10 “furnish controlled substances for other than legitimate medical purposes.” Cal.
11 Health & Safety Code § 11153.5.

12 198. The California State Board of Pharmacy has the authority to “take
13 action against any holder of a license who is guilty of unprofessional conduct”
14 which includes “clearly excessive furnishing of controlled substances” for other
15 than legitimate medical purposes. Cal. Bus. & Prof. Code § 4301(e) (citing Cal.
16 Health & Safety Code § 11153.5). “Factors to be considered in determining whether
17 the furnishing of controlled substances is clearly excessive shall include, but not be
18 limited to, the amount of controlled substances furnished, the previous ordering
19 pattern of the customer (including size and frequency of orders), the type and size
20 of the customer, and where and to whom the customer distributes its product.” *Id.*

21 199. Other examples of unprofessional conduct include procuring a license
22 by fraud or misrepresentation, gross negligence, fraud, making or signing
23 documents with false statements, and violating any state or federal statute or rule
24 regulating controlled substances. Cal. Bus. & Prof. Code § 4301.

25 200. California requires manufacturers and distributors of controlled
26 substances to maintain records of the manufacture and sale of dangerous drugs. *See*
27 Cal. Bus. & Prof. Code §§ 4081; 4161(c)(2)(A); 4332; Cal. Code Regs. tit. 16, §§
28 1780(f); 1783(e).

201. Furthermore, California law incorporates federal requirements set out under the Controlled Substance Act and related controlled substance laws and regulations. *See* Cal. Bus. & Prof. Code §§ 4160(d) (representative-in-charge of wholesaler is responsible for wholesaler's compliance with applicable state and federal laws); 4301(j) (unprofessional conduct includes violating federal laws related to controlled substances); 4301(o) (unprofessional conduct includes violating, attempting to violate, assisting in or abetting or conspiring to violate any applicable federal law); Cal. Code Regs. tit. 16, § 1780(f)(2) (records required for identifying, recording and reporting losses or thefts shall be in accordance with federal regulations).

202. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. California law adopts and incorporates those requirements, as set out above. *See, e.g.,* Cal. Code Regs. tit. 16, 1780(f)(2).

203. Each Distributor Defendant has an affirmative duty under federal and California law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1). California law requires that "[t]he following minimum standards shall apply to all wholesale establishments for which permits have been issued by the Board: . . . (c)(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion." Cal. Code Regs. Tit. 16 § 1780(c)(2). In addition, drug distributors shall "establish, maintain, and adhere to written policies and procedures, which

1 shall be followed for the receipt, security, storage, inventory, and distribution of
2 prescription drugs, including policies and procedures for identifying, recording, and
3 reporting losses or thefts[.]” Cal. Code Regs. Tit. 16 § 1780(f)(1).

4 204. The California Legislature has found that “Protection of the public
5 shall be the highest priority for the California State Board of Pharmacy in exercising
6 its licensing, regulatory, and disciplinary functions. Whenever the protection of the
7 public is inconsistent with other interests sought to be promoted, the protection of
8 the public shall be paramount.” Cal. Bus. & Prof. Code § 4001.1.

9 205. Federal regulations and California law impose a non-delegable duty
10 upon wholesale drug distributors to “design and operate a system to disclose to the
11 registrant suspicious orders of controlled substances. The registrant [distributor]
12 shall inform the Field Division Office of the Administration in his area of suspicious
13 orders when discovered by the registrant. Suspicious orders include orders of
14 unusual size, orders deviating substantially from a normal pattern, and orders of
15 unusual frequency.” 21 C.F.R. § 1301.74(b). *See also* Cal. Bus. & Prof. Code §
16 4169.1 (“A wholesaler, upon discovery, shall notify the board in writing of any
17 suspicious orders of controlled substances placed by a California-licensed
18 pharmacy or wholesaler by providing the board a copy of the information that the
19 wholesaler provides to the United States Drug Enforcement Administration.”); Cal.
20 Health & Safety Code § 11153.5(c) (factors considered in determining if distributor
21 or manufacturer furnished controlled substances with a conscious disregard that
22 they were being used for other than legitimate medical purposes include the amount
23 of controlled substances furnished, the size and frequency of previous orders, the
24 type and size of customer and where the customer distributes the product).

25 206. “Suspicious orders” include orders of an unusual size, orders of
26 unusual frequency or orders deviating substantially from a normal pattern. *See* 21
27 CFR 1301.74(b); *see also* Cal. Bus. & Prof. Code § 4169.1. These criteria are
28 disjunctive and are not all inclusive. For example, if an order deviates substantially

1 from a normal pattern, the size of the order does not matter and the order should be
 2 reported as suspicious. Likewise, a wholesale distributor need not wait for a normal
 3 pattern to develop over time before determining whether a particular order is
 4 suspicious. The size of an order alone, regardless of whether it deviates from a
 5 normal pattern, is enough to trigger the wholesale distributor's responsibility to
 6 report the order as suspicious. The determination of whether an order is suspicious
 7 depends not only on the ordering patterns of the particular customer but also on the
 8 patterns of the entirety of the wholesale distributor's customer base and the patterns
 9 throughout the relevant segment of the wholesale distributor industry.

10 207. In addition to reporting all suspicious orders, distributors must also
 11 stop shipment on any order which is flagged as suspicious and only ship orders
 12 which were flagged as potentially suspicious if, after conducting due diligence, the
 13 distributor can determine that the order is not likely to be diverted into illegal
 14 channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't
 15 Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement*
 16 *Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged
 17 orders must be reported. *Id.*

18 208. These prescription drugs are regulated for the purpose of providing a
 19 "closed" system **intended to reduce the widespread diversion of these drugs out**
 20 **of legitimate channels into the illicit market**, while at the same time providing
 21 the legitimate drug industry with a unified approach to narcotic and dangerous drug
 22 control.¹²⁷

23 209. Different entities supervise the discrete links in the chain that separate
 24 a consumer from a controlled substance. Statutes and regulations define each
 25 participant's role and responsibilities.¹²⁸

26
 27 ¹²⁷ See 1970 U.S.C.C.A.N. 4566, 4571-72.

28 ¹²⁸ Brief for Healthcare Distribution Management Association and National
 Association of Chain Drug Stores as Amici Curiae in Support of Neither Party,
Masters Pharm., Inc. v. U.S. Drug Enf't Admin. (No. 15-1335) (D.C. Cir. Apr. 4,

210. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”¹²⁹

211. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.¹³⁰

212. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, has a “statutory responsibility to exercise

2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, <https://www.healthcaredistribution.org/about> (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, <https://www.nacds.org/about/mission/> (last visited Aug. 21, 2017).

¹²⁹ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

¹³⁰ See Brief for HDMA and NACDS, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”).

1 due diligence to avoid filling suspicious orders that might be diverted into other
 2 than legitimate medical, scientific, and industrial channels.”¹³¹ The letter also
 3 instructs that “distributors must be vigilant in deciding whether a prospective
 4 customer can be trusted to deliver controlled substances only for lawful
 5 purposes.”¹³² The DEA warns that “even just one distributor that uses its DEA
 6 registration to facilitate diversion can cause enormous harm.”¹³³

7 213. The DEA sent a second letter to each of the Distributor Defendants on
 8 December 27, 2007.¹³⁴ This letter reminds the Defendants of their statutory and
 9 regulatory duties to “maintain effective controls against diversion” and “design and
 10 operate a system to disclose to the registrant suspicious orders of controlled
 11 substances.”¹³⁵ The letter further explains:

12 The regulation also requires that the registrant inform the local DEA
 13 Division Office of suspicious orders when discovered by the registrant.
 14 Filing a monthly report of completed transactions (e.g., “excessive
 15 purchase report” or “high unify purchases”) does not meet the
 16 regulatory requirement to report suspicious orders. Registrants are
 17 reminded that their responsibility does not end merely with the filing of
 18 a suspicious order report. Registrants must conduct an independent
 analysis of suspicious orders prior to completing a sale to determine
 whether the controlled substances are likely to be diverted from
 legitimate channels. Reporting an order as suspicious will not absolve
 the registrant of responsibility if the registrant knew, or should have
 known, that the controlled substances were being diverted.

19 The regulation specifically states that suspicious orders include orders
 20 of unusual size, orders deviating substantially from a normal pattern,
 21 and orders of an unusual frequency. These criteria are disjunctive and
 22 are not all inclusive. For example, if an order deviates substantially
 23 from a normal pattern, the size of the order does not matter and the
 order should be reported as suspicious. Likewise, a registrant need not
 wait for a “normal pattern” to develop over time before determining
 whether a particular order is suspicious. The size of an order alone,

24 ¹³¹ Rannazzisi Letter, at 2.

25 ¹³² *Id.* at 1.

26 ¹³³ *Id.* at 2.

27 ¹³⁴ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of
 Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health
 (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW
 (D.D.C. Feb. 10, 2012), ECF No. 14-8.

28 ¹³⁵ *Id.*

whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.¹³⁶

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."¹³⁷

214. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled

¹³⁶ *Id.*

¹³⁷ *Id.*

1 prescription drugs, but undertake such efforts as responsible members of
2 society.”¹³⁸

3 215. The Distributor Defendants knew they were required to monitor,
4 detect, and halt suspicious orders. Industry compliance guidelines established by
5 the Healthcare Distribution Management Association, the trade association of
6 pharmaceutical distributors, explain that distributors are “[a]t the center of a
7 sophisticated supply chain” and therefore “are uniquely situated to perform due
8 diligence in order to help support the security of the controlled substances they
9 deliver to their customers.” The guidelines set forth recommended steps in the “due
10 diligence” process, and note in particular: If an order meets or exceeds a
11 distributor’s threshold, as defined in the distributor’s monitoring system, or is
12 otherwise characterized by the distributor as an order of interest, the distributor
13 should not ship to the customer, in fulfillment of that order, any units of the specific
14 drug code product as to which the order met or exceeded a threshold or as to which
15 the order was otherwise characterized as an order of interest.¹³⁹

16 216. Each of the Distributor Defendants sold prescription opioids, including
17 hydrocodone and/or oxycodone, to retailers in Plaintiffs’ Community and/or to
18 retailers from which Defendants knew prescription opioids were likely to be
19 diverted to Plaintiffs’ Community.

20 217. Each Distributor Defendant owes a duty to monitor and detect
21 suspicious orders of prescription opioids.

22 218. Each Distributor Defendant owes a duty under federal and state law to
23 investigate and refuse suspicious orders of prescription opioids.

24
25
26 ¹³⁸ See Brief of HDMA, 2012 WL 1637016, at *2.

27 ¹³⁹ Healthcare Distribution Management Association (HDMA) Industry
28 Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of
Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C.
Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

1 219. Each Distributor Defendant owes a duty under federal and state law to
2 report suspicious orders of prescription opioids.

3 220. Each Distributor Defendant owes a duty under federal and state law to
4 prevent the diversion of prescription opioids into illicit markets in the State and
5 Plaintiffs' Community.

6 221. The foreseeable harm resulting from a breach of these duties is the
7 diversion of prescription opioids for nonmedical purposes and subsequent plague
8 of opioid addiction.

9 222. The foreseeable harm resulting from the diversion of prescription
10 opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in
11 Plaintiffs' Community and the damages caused thereby.

12 **2. The Distributor Defendants Breached Their Duties.**

13 223. Because distributors handle such large volumes of controlled
14 substances, and are the first major line of defense in the movement of legal
15 pharmaceutical controlled substances from legitimate channels into the illicit
16 market, it is incumbent on distributors to maintain effective controls to prevent
17 diversion of controlled substances. Should a distributor deviate from these checks
18 and balances, the closed system collapses.¹⁴⁰

19 224. The sheer volume of prescription opioids distributed to pharmacies in
20 the Plaintiffs' Community, and/or to pharmacies from which the Distributor
21 Defendants knew the opioids were likely to be diverted into Plaintiffs' Community,
22 is excessive for the medical need of the community and facially suspicious. Some
23 red flags are so obvious that no one who engages in the legitimate distribution of
24 controlled substances can reasonably claim ignorance of them.¹⁴¹

25
26 ¹⁴⁰ See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-
27 cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

28 ¹⁴¹ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015)
(citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed.
Reg. 62,316, 62,322 (2012)).

1 225. The Distributor Defendants failed to report “suspicious orders”
2 originating from Plaintiffs’ Community, or which the Distributor Defendants knew
3 were likely to be diverted to Plaintiffs’ Community, to the federal and state
4 authorities, including the DEA and/or the state Board of Pharmacy.

5 226. The Distributor Defendants unlawfully filled suspicious orders of
6 unusual size, orders deviating substantially from a normal pattern and/or orders of
7 unusual frequency in Plaintiffs’ Community, and/or in areas from which the
8 Distributor Defendants knew opioids were likely to be diverted to Plaintiffs’
9 Community.

10 227. The Distributor Defendants breached their duty to monitor, detect,
11 investigate, refuse and report suspicious orders of prescription opiates originating
12 from Plaintiffs’ Community, and/or in areas from which the Distributor Defendants
13 knew opioids were likely to be diverted to Plaintiffs’ Community.

14 228. The Distributor Defendants breached their duty to maintain effective
15 controls against diversion of prescription opiates into other than legitimate medical,
16 scientific, and industrial channels.

17 229. The Distributor Defendants breached their duty to “design and operate
18 a system to disclose to the registrant suspicious orders of controlled substances”
19 and failed to inform the authorities including the DEA of suspicious orders when
20 discovered, in violation of their duties under federal and state law.

21 230. The Distributor Defendants breached their duty to exercise due
22 diligence to avoid filling suspicious orders that might be diverted into channels
23 other than legitimate medical, scientific and industrial channels.¹⁴²

24 231. The federal and state laws at issue here are public safety laws.

25 232. The Distributor Defendants’ violations of public safety statutes
26 constitute prima facie evidence of negligence under State law.

27
28 ¹⁴² See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

1 233. The Distributor Defendants supplied prescription opioids to obviously
2 suspicious physicians and pharmacies, enabled the illegal diversion of opioids,
3 aided criminal activity, and disseminated massive quantities of prescription opioids
4 into the black market.

5 234. The unlawful conduct by the Distributor Defendants is purposeful and
6 intentional. The Distributor Defendants refuse to abide by the duties imposed by
7 federal and state law which are required to legally acquire and maintain a license to
8 distribute prescription opiates.

9 235. The Distributor Defendants acted with actual malice in breaching their
10 duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of
11 other persons, and said actions have a great probability of causing substantial harm.

12 236. The Distributor Defendants' repeated shipments of suspicious orders,
13 over an extended period of time, in violation of public safety statutes, and without
14 reporting the suspicious orders to the relevant authorities demonstrates wanton,
15 willful, or reckless conduct or criminal indifference to civil obligations affecting
16 the rights of others.

17 **3. The Distributor Defendants Have Sought to Avoid and Have**
18 **Misrepresented their Compliance with Their Legal Duties.**

19 237. The Distributor Defendants have repeatedly misrepresented their
20 compliance with their legal duties under state and federal law and have wrongfully
21 and repeatedly disavowed those duties in an effort to mislead regulators and the
22 public regarding the Distributor Defendants' compliance with their legal duties.

23 238. Distributor Defendants have refused to recognize any duty beyond
24 *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade
25 association run by the Distributor Defendants, and the NACDS submitted amicus
26 briefs regarding the legal duty of wholesale distributors. Inaccurately denying the
27 legal duties that the wholesale drug industry has been tragically recalcitrant in
28 performing, they argued as follows:

- a. The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”¹⁴³
- b. The Associations argued that, “DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications.”¹⁴⁴
- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”¹⁴⁵
- d. The Association complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”¹⁴⁶
- e. The Associations alleged (inaccurately) that “DEA’s regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”¹⁴⁷
- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”¹⁴⁸

239. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.¹⁴⁹

¹⁴³ Brief for HDMA and NACDS, 2016 WL 1321983, at *4–5.

¹⁴⁴ *Id.* at *8 (citations and quotation marks omitted).

¹⁴⁵ *Id.* at *14.

¹⁴⁶ *Id.* at *22.

¹⁴⁷ *Id.* at *24–25.

¹⁴⁸ *Id.* at *26.

¹⁴⁹ See Brief of HDMA, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry “does not know the rules of the road because” they claim (inaccurately) that the “DEA has not adequately explained them”).

240. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id.* at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstances prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

241. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."¹⁵⁰ Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within

¹⁵⁰ See Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

1 those pharmacies had failed to fulfill their corresponding responsibility to ensure
 2 that controlled substances were dispensed pursuant to prescriptions issued for
 3 legitimate medical purposes by practitioners acting in the usual course of their
 4 professional practice, as required by 21 C.F.R § 1306.04(a).”¹⁵¹ McKesson admitted
 5 that, during this time period, it “failed to maintain effective controls against
 6 diversion of particular controlled substances into other than legitimate medical,
 7 scientific and industrial channels by sales to certain of its customers in violation of
 8 the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at
 9 the McKesson Distribution Centers.”¹⁵² Due to these violations, McKesson agreed
 10 that its authority to distribute controlled substances from numerous facilities would
 11 be partially suspended.¹⁵³

12 242. The 2017 Memorandum of Agreement followed a 2008 Settlement
 13 Agreement in which McKesson also admitted failure to report suspicious orders of
 14 controlled substances to the DEA.¹⁵⁴ In the 2008 Settlement Agreement, McKesson
 15 “recognized that it had a duty to monitor its sales of all controlled substances and
 16 report suspicious orders to DEA,” but had failed to do so.¹⁵⁵ The 2017
 17 Memorandum of Agreement documents that McKesson continued to breach its
 18 admitted duties by “fail[ing] to properly monitor its sales of controlled substances
 19 and/or report suspicious orders to DEA, in accordance with McKesson’s
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25 ¹⁵¹ *Id.* at 4.

26 ¹⁵² *Id.*

27 ¹⁵³ *Id.* at 6.

28 ¹⁵⁴ *Id.* at 4.

¹⁵⁵ *Id.*

obligations.”¹⁵⁶ As a result of these violations, McKesson was fined and required to pay to the United States \$150,000,000.¹⁵⁷

243. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

244. Because of the Distributor Defendants’ refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.¹⁵⁸ The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.¹⁵⁹ These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

¹⁵⁶ *Id.*; see also Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] (“McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.”), <https://www.justice.gov/opa/press-release/file/928471/download>.

¹⁵⁷ See 2017 Settlement Agreement and Release, at 6.

¹⁵⁸ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

¹⁵⁹ *Id.*

- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

1 245. Rather than abide by their non-delegable duties under public safety
 2 laws, the Distributor Defendants, individually and collectively through trade groups
 3 in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and
 4 lobbied Congress to strip the DEA of its ability to immediately suspend distributor
 5 registrations. The result was a “sharp drop in enforcement actions” and the passage
 6 of the “Ensuring Patient Access and Effective Drug Enforcement Act” which,
 7 ironically, raised the burden for the DEA to revoke a distributor’s license from
 8 “imminent harm” to “immediate harm” and provided the industry the right to “cure”
 9 any violations of law before a suspension order can be issued.¹⁶⁰

10 246. In addition to taking actions to limit regulatory prosecutions and
 11 suspensions, the Distributor Defendants undertook to fraudulently convince the
 12 public that they were complying with their legal obligations, including those
 13 imposed by licensing regulations. Through such statements, the Distributor
 14 Defendants attempted to assure the public they were working to curb the opioid
 15 epidemic.

16 247. For example, a Cardinal Health executive claimed that it uses
 17 “advanced analytics” to monitor its supply chain, and represented that it was being
 18 “as effective and efficient as possible in constantly monitoring, identifying, and
 19 eliminating any outside criminal activity.”¹⁶¹ Given the sales volumes and the
 20

21 ¹⁶⁰ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed*
 22 *Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct.
 23 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham,
 24 *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown*
 25 *Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017,
 26 https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV*
 27 *Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017,
 28 <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

¹⁶¹ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the*
Hands of Illegal Users: “No One Was Doing Their Job,” Wash. Post, Oct. 22,
 2016, <https://www.washingtonpost.com/investigations/how-drugs-intended-for->

1 company's history of violations, this executive was either not telling the truth, or,
2 if Cardinal Health had such a system, it ignored the results.

3 248. Similarly, Defendant McKesson publicly stated that it has a "best-in-
4 class controlled substance monitoring program to help identify suspicious orders,"
5 and claimed it is "deeply passionate about curbing the opioid epidemic in our
6 country."¹⁶² Again, given McKesson's historical conduct, this statement is either
7 false, or the company ignored outputs of the monitoring program.

8 249. By misleading the public about the effectiveness of their controlled
9 substance monitoring programs, the Distributor Defendants successfully concealed
10 the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert.
11 The Plaintiffs did not know of the existence or scope of Defendants' industry-wide
12 fraud and could not have acquired such knowledge earlier through the exercise of
13 reasonable diligence.

14 250. Meanwhile, the opioid epidemic rages unabated in the Nation, the
15 State, and in Plaintiffs' Community.

16 251. The epidemic still rages because the fines and suspensions imposed by
17 the DEA do not change the conduct of the industry. The distributors, including the
18 Distributor Defendants, pay fines as a cost of doing business in an industry that
19 generates billions of dollars in annual revenue. They hold multiple DEA registration
20 numbers and when one facility is suspended, they simply ship from another facility.

21 252. The wrongful actions and omissions of the Distributor Defendants
22 which have caused the diversion of opioids and which have been a substantial
23
24

25 patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-
26 job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

27 ¹⁶² Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as*
28 *the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016,
https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

1 contributing factor to and/or proximate cause of the opioid crisis are alleged in
2 greater detail in the racketeering allegations below.

3 253. The Distributor Defendants have abandoned their duties imposed
4 under federal and state law, taken advantage of a lack of DEA law enforcement,
5 and abused the privilege of distributing controlled substances in the State and
6 Plaintiffs' Community.

7 **4. The National Retail Pharmacies Were on Notice of and**
8 **Contributed to Illegal Diversion of Prescription Opioids**

9 254. National retail pharmacy chains earned enormous profits by flooding
10 the country with prescription opioids.¹⁶³ They were keenly aware of the oversupply
11 of prescription opioids through the extensive data and information they developed
12 and maintained as both distributors and dispensaries. Yet, instead of taking any
13 meaningful action to stem the flow of opioids into communities, they continued to
14 participate in the oversupply and profit from it.

15 255. Each of the National Retail Pharmacies does substantial business
16 throughout the United States. This business includes the distribution and dispensing
17 of prescription opioids.

18 256. On information and belief, the National Retail Pharmacies distributed
19 and dispensed substantial quantities of prescription opioids, including fentanyl,
20 hydrocodone, and oxycodone in California. In addition, they distributed and
21 dispensed substantial quantities of prescription opioids in other states, and these
22 drugs were diverted from these other states to California. The National Retail
23 Pharmacies failed to take meaningful action to stop this diversion despite their
24 knowledge of it, and contributed substantially to the diversion problem.

25
26
27 ¹⁶³ The allegations contained in this Complaint are based, in part, on discovery that
28 is in its infancy. Plaintiffs do not have access to transactional ARCOS data for
California. Accordingly, Plaintiffs reserve their right to further amend this
complaint to add supporting allegations, claims and parties.

1 257. The National Retail Pharmacies developed and maintained extensive
 2 data on opioids they distributed and dispensed. Through this data, National Retail
 3 Pharmacies had direct knowledge of patterns and instances of improper distribution,
 4 prescribing, and use of prescription opioids in communities throughout the country,
 5 and in California in particular. They used the data to evaluate their own sales
 6 activities and workforce. On information and belief, the National Retail Pharmacies
 7 also provided Defendants with data regarding, *inter alia*, individual doctors in
 8 exchange for rebates or other forms of consideration. The National Retail
 9 Pharmacies' data is a valuable resource that they could have used to help stop
 10 diversion, but failed to do so.

11 **a. The National Retail Pharmacies Have a Duty to Prevent Diversion**

12 258. Each participant in the supply chain of opioid distribution, including
 13 the National Retail Pharmacies, is responsible for preventing diversion of
 14 prescription opioids into the illegal market by, among other things, monitoring and
 15 reporting suspicious activity.

16 259. The National Retail Pharmacies, like manufacturers and other
 17 distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA,
 18 pharmacy registrants are required to "provide effective controls and procedures to
 19 guard against theft and diversion of controlled substances." See 21 C.F.R. §
 20 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the
 21 proper prescribing and dispensing of controlled substances is upon the prescribing
 22 practitioner, but a corresponding responsibility rests with the pharmacist who fills
 23 the prescription." Because pharmacies themselves are registrants under the CSA,
 24 the duty to prevent diversion lies with the pharmacy entity, not the individual
 25 pharmacist alone.

26 260. The DEA, among others, has provided extensive guidance to
 27 pharmacies concerning their duties to the public. The guidance advises pharmacies
 28 how to identify suspicious orders and other evidence of diversion.

1 261. Suspicious pharmacy orders include orders of unusually large size,
2 orders that are disproportionately large in comparison to the population of a
3 community served by the pharmacy, orders that deviate from a normal pattern
4 and/or orders of unusual frequency and duration, among others.

5 262. Additional types of suspicious orders include: (1) prescriptions written
6 by a doctor who writes significantly more prescriptions (or in larger quantities or
7 higher doses) for controlled substances compared to other practitioners in the area;
8 (2) prescriptions which should last for a month in legitimate use, but are being
9 refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as
10 depressants and stimulants, at the same time; (4) prescriptions that look “too good”
11 or where the prescriber’s handwriting is too legible; (5) prescriptions with quantities
12 or doses that differ from usual medical usage; (6) prescriptions that do not comply
13 with standard abbreviations and/or contain no abbreviations; (7) photocopied
14 prescriptions; or (8) prescriptions containing different handwriting. Most of the
15 time, these attributes are not difficult to detect and should be easily recognizable by
16 pharmacies.

17 263. Suspicious pharmacy orders are red flags for if not direct evidence of
18 diversion.

19 264. Other signs of diversion can be observed through data gathered,
20 consolidated, and analyzed by the National Retail Pharmacies themselves. That
21 data allows them to observe patterns or instances of dispensing that are potentially
22 suspicious, of oversupply in particular stores or geographic areas, or of prescribers
23 or facilities that seem to engage in improper prescribing.

24 265. According to industry standards, if a pharmacy finds evidence of
25 prescription diversion, the local Board of Pharmacy and DEA must be contacted.

26 266. Despite their legal obligations as registrants under the CSA, the
27 National Retail Pharmacies allowed widespread diversion to occur—and they did
28 so knowingly.

1 267. Performance metrics and prescription quotas adopted by the National
2 Retail Pharmacies for their retail stores contributed to their failure. Under CVS's
3 Metrics System, for example, pharmacists are directed to meet high goals that make
4 it difficult, if not impossible, to comply with applicable laws and regulations. There
5 is no measurement for pharmacy accuracy or customer safety. Moreover, the
6 bonuses for pharmacists are calculated, in part, on how many prescriptions that
7 pharmacist fills within a year. The result is both deeply troubling and entirely
8 predictable: opioids flowed out of National Retail Pharmacies and into communities
9 throughout the country. The policies remained in place even as the epidemic raged.

10 268. Upon information and belief, this problem was compounded by the
11 Pharmacies' failure to adequately train their pharmacists and pharmacy technicians
12 on how to properly and adequately handle prescriptions for opioid painkillers,
13 including what constitutes a proper inquiry into whether a prescription is legitimate,
14 whether a prescription is likely for a condition for which the FDA has approved
15 treatments with opioids, and what measures and/or actions to take when a
16 prescription is identified as phony, false, forged, or otherwise illegal, or when
17 suspicious circumstances are present, including when prescriptions are procured
18 and pills supplied for the purpose of illegal diversion and drug trafficking.

19 269. Upon information and belief, the National Retail Pharmacies also
20 failed to adequately use data available to them to identify doctors who were writing
21 suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of
22 opioids, or to adequately use data available to them to do statistical analysis to
23 prevent the filling of prescriptions that were illegally diverted or otherwise
24 contributed to the opioid crisis.

25 270. Upon information and belief, the National Retail Pharmacies failed to
26 analyze: (a) the number of opioid prescriptions filled by individual pharmacies
27 relative to the population of the pharmacy's community; (b) the increase in opioid
28 sales relative to past years; (c) the number of opioid prescriptions filled relative to

1 other drugs; and (d) the increase in annual opioid sales relative to the increase in
2 annual sales of other drugs.

3 271. Upon information and belief, the National Retail Pharmacies also
4 failed to conduct adequate internal or external audits of their opioid sales to identify
5 patterns regarding prescriptions that should not have been filled and to create
6 policies accordingly, or if they conducted such audits, they failed to take any
7 meaningful action as a result.

8 272. Upon information and belief, the National Retail Pharmacies also
9 failed to effectively respond to concerns raised by their own employees regarding
10 inadequate policies and procedures regarding the filling of opioid prescriptions.

11 273. The National Retail Pharmacies were, or should have been, fully aware
12 that the quantity of opioids being distributed and dispensed by them was untenable,
13 and in many areas patently absurd; yet, they did not take meaningful action to
14 investigate or to ensure that they were complying with their duties and obligations
15 under the law with regard to controlled substances.

16 **b. Multiple Enforcement Actions against the National Retail**
17 **Pharmacies Confirm their Compliance Failures.**

18 274. The National Retail Pharmacies have long been on notice of their
19 failure to abide by state and federal law and regulations governing the distribution
20 and dispensing of prescription opioids. Indeed, several of the National Retail
21 Pharmacies have been repeatedly penalized for their illegal prescription opioid
22 practices. Upon information and belief, based upon the widespread nature of these
23 violations, these enforcement actions are the product of, and confirm, national
24 policies and practices of the National Retail Pharmacies.

25 **i. CVS**

26 275. CVS is one of the largest companies in the world, with annual revenue
27 of more than \$150 billion. According to news reports, it manages medications for
28 nearly 90 million customers at 9,700 retail locations. CVS could be a force for good

1 in connection with the opioid crisis, but like other Defendants, CVS sought profits
2 over people.

3 276. CVS is a repeat offender and recidivist: the company has paid fines
4 totaling over \$40 million as the result of a series of investigations by the DEA and
5 the United States Department of Justice (“DOJ”). It nonetheless treated these fines
6 as the cost of doing business and has allowed its pharmacies to continue dispensing
7 opioids in quantities significantly higher than any plausible medical need would
8 require, and to continue violating its recordkeeping and dispensing obligations
9 under the CSA.

10 277. As recently as July 2017, CVS entered into a \$5 million settlement
11 with the U.S. Attorney’s Office for the Eastern District of California regarding
12 allegations that its pharmacies failed to keep and maintain accurate records of
13 Schedule II, III, IV, and V controlled substances.¹⁶⁴

14 278. This fine was preceded by numerous others throughout the country.

15 279. In February 2016, CVS paid \$8 million to settle allegations made by
16 the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in
17 Maryland violated their duties under the CSA and filled prescriptions with no
18 legitimate medical purpose.¹⁶⁵

19 280. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ
20 that stores in Connecticut failed to maintain proper records in accordance with the
21 CSA.¹⁶⁶

23 ¹⁶⁴ Press Release, U.S. Attorney’s Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays*
24 *\$5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep’t of
Just. (July 11, 2017), [https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-](https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act)
25 [pays-5m-settle-alleged-violations-controlled-substance-act](https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act).

26 ¹⁶⁵ Press Release, U.S. Attorney’s Office Dist. of Md., *United States Reaches \$8*
27 *Million Settlement Agreement with CVS for Unlawful Distribution of Controlled*
Substances, U.S. Dep’t of Just. (Feb. 12, 2016), [https://www.justice.gov/usao-](https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled)
md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-
distribution-controlled.

28 ¹⁶⁶ Press Release, U.S. Attorney’s Office Dist. of Conn., *CVS Pharmacy Pays*
\$600,000 to Settle Controlled Substances Act Allegations, U.S. Dep’t of Just. (Oct.

1 281. In September 2016, CVS entered into a \$795,000 settlement with the
2 Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to
3 access the state's prescription monitoring program website and review a patient's
4 prescription history before dispensing certain opioid drugs.¹⁶⁷

5 282. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve
6 allegations that 50 of its stores violated the CSA by filling forged prescriptions for
7 controlled substances—mostly addictive painkillers—more than 500 times between
8 2011 and 2014.¹⁶⁸

9 283. In August 2015, CVS entered into a \$450,000 settlement with the U.S.
10 Attorney's Office for the District of Rhode Island to resolve allegations that several
11 of its Rhode Island stores violated the CSA by filling invalid prescriptions and
12 maintaining deficient records. The United States alleged that CVS retail pharmacies
13 in Rhode Island filled a number of forged prescriptions with invalid DEA numbers,
14 and filled multiple prescriptions written by psychiatric nurse practitioners for
15 hydrocodone, despite the fact that these practitioners were not legally permitted to
16 prescribe that drug. Additionally, the government alleged that CVS had
17 recordkeeping deficiencies.¹⁶⁹

18 284. In May 2015, CVS agreed to pay a \$22 million penalty following a
19 DEA investigation that found that employees at two pharmacies in Sanford, Florida,
20

21 20, 2016), [https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-](https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-act-allegations)
22 [controlled-substances-act-allegations](https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-act-allegations).

23 ¹⁶⁷ Dialynn Dwyer, *CVS will pay \$795,000, strengthen policies around dispensing*
24 *opioids in agreement with state*, Boston.com (Sept. 1, 2016),
[https://www.boston.com/news/local-news/2016/09/01/cvs-will-pay-795000-](https://www.boston.com/news/local-news/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-in-agreement-with-state)
[strengthen-policies-around-dispensing-opioids-in-agreement-with-state](https://www.boston.com/news/local-news/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-in-agreement-with-state).

25 ¹⁶⁸ Press Release, U.S. Attorney's Office Dist. of Mass., *CVS to Pay \$3.5 Million*
26 *to Resolve Allegations that Pharmacists Filled Fake Prescriptions*, U.S. Dep't of
Just. (June 30, 2016), [https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-](https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions)
[resolve-allegations-pharmacists-filled-fake-prescriptions](https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions).

27 ¹⁶⁹ Press Release, U.S. Attorney's Office Dist. of R.I., *Drug Diversion Claims*
28 *Against CVS Health Corp. Resolved With \$450,000 Civil Settlement*, U.S. Dep't
of Just. (Aug. 10, 2015), [https://www.justice.gov/usao-ri/pr/drug-diversion-claims-](https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement)
[against-cvs-health-corp-resolved-450000-civil-settlement](https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement).

1 had dispensed prescription opioids, “based on prescriptions that had not been issued
2 for legitimate medical purposes by a health care provider acting in the usual course
3 of professional practice. CVS also acknowledged that its retail pharmacies had a
4 responsibility to dispense only those prescriptions that were issued based on
5 legitimate medical need.”¹⁷⁰

6 285. In September 2014, CVS agreed to pay \$1.9 million in civil penalties
7 to resolve allegations it filled prescriptions written by a doctor whose controlled-
8 substance registration had expired.¹⁷¹

9 286. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy
10 Board for improperly selling prescription narcotics in at least five locations in the
11 Oklahoma City metropolitan area.¹⁷²

12 287. Dating back to 2006, CVS retail pharmacies in Oklahoma and
13 elsewhere intentionally violated the CSA by filling prescriptions signed by
14 prescribers with invalid DEA registration numbers.¹⁷³

15 **ii. Walgreens**

16 288. Walgreens is the second-largest pharmacy store chain in the United
17 States behind CVS, with annual revenue of more than \$118 billion. According to
18
19

20
21 ¹⁷⁰ Press Release, U.S. Attorney’s Office M. Dist. of Fla., United States Reaches
22 \$22 Million Settlement Agreement With CVS For Unlawful Distribution of
23 Controlled Substances, U.S. Dep’t of Just. (May 13, 2015),
[https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-](https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution)
[agreement-cvs-unlawful-distribution.](https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution)

24 ¹⁷¹ Patrick Danner, *H-E-B, CVS Fined Over Prescriptions*, San Antonio Express-
25 News (Sept. 5, 2014), [http://www.expressnews.com/business/local/article/H-E-](http://www.expressnews.com/business/local/article/H-E-BCVS-fined-over-prescriptions-5736554.php)
[BCVS-fined-over-prescriptions-5736554.php.](http://www.expressnews.com/business/local/article/H-E-BCVS-fined-over-prescriptions-5736554.php)

26 ¹⁷² Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines*
27 *at times*, NewsOK (May 3, 2015), [http://newsok.com/article/5415840.](http://newsok.com/article/5415840)

28 ¹⁷³ Press Release, U.S. Attorney’s Office W. Dist. of Okla., CVS to Pay \$11
Million To Settle Civil Penalty Claims Involving Violations of Controlled
Substances Act, U.S. Dep’t of Just. (Apr. 3, 2013), [https://www.justice.gov/usao-](https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled)
[wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-](https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled)
[controlled.](https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled)

1 its website, Walgreens operates more than 8,100 retail locations and filled 990
2 million prescriptions on a 30-day adjusted basis in fiscal 2017.

3 289. Walgreens also has been penalized for serious and flagrant violations
4 of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—
5 \$80 million—to resolve allegations that it committed an unprecedented number of
6 recordkeeping and dispensing violations of the CSA, including negligently allowing
7 controlled substances such as oxycodone and other prescription painkillers to be
8 diverted for abuse and illegal black market sales.¹⁷⁴

9 290. The settlement resolved investigations into and allegations of CSA
10 violations in Florida, New York, Michigan, and Colorado that resulted in the
11 diversion of millions of opioids into illicit channels.

12 291. Walgreens' Florida operations at issue in this settlement highlight its
13 egregious conduct regarding diversion of prescription opioids. Walgreens' Florida
14 pharmacies each allegedly ordered more than one million dosage units of
15 oxycodone in 2011—more than ten times the average amount.¹⁷⁵

16 292. They increased their orders over time, in some cases as much as 600%
17 in the space of just two years, including, for example, supplying a town of 3,000
18 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate
19 officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens
20 suggested, in reviewing the legitimacy of prescriptions coming from pain clinics,
21 that “if these are legitimate indicators of inappropriate prescriptions perhaps we
22 should consider not documenting our own potential noncompliance,” underscoring
23
24

25 ¹⁷⁴ Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay*
26 *A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled*
27 *Substances Act*, U.S. Dep't of Just. (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled>.

28 ¹⁷⁵ Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

1 Walgreens' attitude that profit outweighed compliance with the CSA or the health
2 of communities.¹⁷⁶

3 293. Defendant Walgreens' settlement with the DEA stemmed from the
4 DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which
5 was responsible for significant opioid diversion in Florida. According to the Order
6 to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase
7 the number of oxycodone sales to Walgreens' Florida pharmacies, and provided
8 bonuses for pharmacy employees based on number of prescriptions filled at the
9 pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant
10 Walgreens ranked all of its Florida stores by number of oxycodone prescriptions
11 dispensed in June of that year, and found that the highest-ranking store in
12 oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these
13 prescriptions were filled by the Jupiter Center.¹⁷⁷

14 294. Walgreens has also settled with a number of state attorneys general,
15 including West Virginia (\$575,000) and Massachusetts (\$200,000).¹⁷⁸

16 295. The Massachusetts Attorney General's Medicaid Fraud Division
17 found that, from 2010 through most of 2015, multiple Walgreens stores across the
18 state failed to monitor the opioid use of some Medicaid patients who were
19 considered high-risk.

20 296. In January 2017, an investigation by the Massachusetts Attorney
21 General found that some Walgreens pharmacies failed to monitor patients' drug use
22 patterns and didn't use sound professional judgment when dispensing opioids and
23 other controlled substances—despite the context of soaring overdose deaths in
24

25 ¹⁷⁶ *Id.*

26 ¹⁷⁷ *Id.*

27 ¹⁷⁸ *Walgreens to pay \$200,000 settlement for lapses with opioids*, APhA (Jan. 25,
28 2017), <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>.

Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.¹⁷⁹

iii. Rite Aid

297. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.

298. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.¹⁸⁰

299. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that led to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).¹⁸¹

300. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

301. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operating procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

¹⁷⁹ *Id.*

¹⁸⁰ Press Release, Dep't of Just., *Rite Aid Corporation and Subsidiaries Agree to Pay \$5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act*, U.S. Dep't of Just. (Jan. 12, 2009), <https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations>.

¹⁸¹ *Id.*

1 302. Throughout the country and the State, the National Retail Pharmacies
2 were or should have been aware of numerous red flags of potential suspicious
3 activity and diversion.

4 303. On information and belief, from the catbird seat of their retail
5 pharmacy operations, the National Retail Pharmacies knew or reasonably should
6 have known about the disproportionate flow of opioids into California and the
7 operation of “pill mills” that generated opioid prescriptions that, by their quantity
8 or nature, were red flags for if not direct evidence of illicit supply and diversion.
9 Additional information was provided by news reports, and state and federal
10 regulatory actions, including prosecutions of pill mills in the area.

11 304. On information and belief, the National Retail Pharmacies knew or
12 reasonably should have known about the devastating consequences of the
13 oversupply and diversion of prescription opioids, including spiking opioid overdose
14 rates in the community.

15 305. On information and belief, because of (among others sources of
16 information) regulatory and other actions taken against the National Retail
17 Pharmacies directly, actions taken against others pertaining to prescription opioids
18 obtained from their retail stores, complaints and information from employees and
19 other agents, and the massive volume of opioid prescription drug sale data that they
20 developed and monitored, the National Retail Pharmacies were well aware that their
21 distribution and dispensing activities fell far short of legal requirements.

22 306. The National Retail Pharmacies’ actions and omission in failing to
23 effectively prevent diversion and failing to monitor, report, and prevent suspicious
24 orders have contributed significantly to the opioid crisis by enabling, and failing to
25 prevent, the diversion of opioids.

**D. THE MANUFACTURER DEFENDANTS’ UNLAWFUL FAILURE
TO PREVENT DIVERSION AND MONITOR, REPORT, AND
PREVENT SUSPICIOUS ORDERS.**

307. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal law.

308. Under federal law, the Manufacturing Defendants were required to comply with the same licensing requirements and with the same rules regarding prevention of diversion and reporting suspicious orders, as set out above.

309. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . . .

21 U.S.C. § 823(a)(1) (emphasis added).

310. Additionally, as “registrants” under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part

1 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is
 2 registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823
 3 or 958).” Like the Distributor Defendants, the Manufacture Defendants breached
 4 these duties.

5 311. The Manufacturer Defendants had access to and possession of the
 6 information necessary to monitor, report, and prevent suspicious orders and to
 7 prevent diversion. The Manufacturer Defendants engaged in the practice of paying
 8 “chargebacks” to opioid distributors. A chargeback is a payment made by a
 9 manufacturer to a distributor after the distributor sells the manufacturer’s product
 10 at a price below a specified rate. After a distributor sells a manufacturer’s product
 11 to a pharmacy, for example, the distributor requests a chargeback from the
 12 manufacturer and, in exchange for the payment, the distributor identifies to the
 13 manufacturer the product, volume and the pharmacy to which it sold the product.
 14 Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew
 15 – the volume, frequency, and pattern of opioid orders being placed and filled. The
 16 Manufacturer Defendants built receipt of this information into the payment
 17 structure for the opioids provided to the opioid distributors.

18 312. Federal statutes and regulations are clear: just like opioid distributors,
 19 opioid manufacturers are required to “design and operate a system to disclose . . .
 20 suspicious orders of controlled substances” and to maintain “effective controls
 21 against diversion.” 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

22 313. The Department of Justice has recently confirmed the suspicious order
 23 obligations clearly imposed by federal law upon opioid manufacturers, fining
 24 Mallinckrodt \$35 million for failure to report suspicious orders of controlled
 25 substances, including opioids, and for violating recordkeeping requirements.¹⁸²
 26

27
 28 ¹⁸² See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record
 \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical
 Drugs and for Recordkeeping Violations (July 11, 2017),

1 314. In the press release accompanying the settlement, the Department of
 2 Justice stated: Mallinckrodt “did not meet its obligations to detect and notify DEA
 3 of suspicious orders of controlled substances such as oxycodone, the abuse of which
 4 is part of the current opioid epidemic. These suspicious order monitoring
 5 requirements exist to prevent excessive sales of controlled substances, like
 6 oxycodone Mallinckrodt’s actions and omissions formed a link in the chain of
 7 supply that resulted in millions of oxycodone pills being sold on the street. . . .
 8 ‘Manufacturers and distributors have a crucial responsibility to ensure that
 9 controlled substances do not get into the wrong hands. . . .’”¹⁸³

10 315. Among the allegations resolved by the settlement, the government
 11 alleged “Mallinckrodt failed to design and implement an effective system to detect
 12 and report ‘suspicious orders’ for controlled substances – orders that are unusual in
 13 their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors,
 14 and the distributors then supplied various U.S. pharmacies and pain clinics, an
 15 increasingly excessive quantity of oxycodone pills without notifying DEA of these
 16 suspicious orders.”¹⁸⁴

17 316. The Memorandum of Agreement entered into by Mallinckrodt (“2017
 18 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a
 19 responsibility to maintain effective controls against diversion, including a
 20 requirement that it review and monitor these sales and report suspicious orders to
 21 DEA.”¹⁸⁵

22
 23
 24 [https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-](https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders)
 25 [settlement-failure-report-suspicious-orders.](https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders)

26 ¹⁸³ *Id.* (quoting DEA Acting Administrator Chuck Rosenberg).

27 ¹⁸⁴ *Id.*

28 ¹⁸⁵ Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download> (“2017 Mallinckrodt MOA”).

1 317. The 2017 Mallinckrodt MOA further details the DEA's allegations
2 regarding Mallinckrodt's failures to fulfill its legal duties as an opioid
3 manufacturer:

4 With respect to its distribution of oxycodone and hydrocodone
5 products, Mallinckrodt's alleged failure to distribute these controlled
6 substances in a manner authorized by its registration and Mallinckrodt's
7 alleged failure to operate an effective suspicious order monitoring
8 system and to report suspicious orders to the DEA when discovered as
9 required by and in violation of 21 C.F.R. § 1301.74(b). The above
10 includes, but is not limited to Mallinckrodt's alleged failure to:

- 11 i. conduct adequate due diligence of its customers;
- 12 ii. detect and report to the DEA orders of unusual size and
13 frequency;
- 14 iii. detect and report to the DEA orders deviating substantially from
15 normal patterns including, but not limited to, those identified in
16 letters from the DEA Deputy Assistant Administrator, Office of
17 Diversion Control, to registrants dated September 27, 2006 and
18 December 27, 2007:
 - 19 1. orders that resulted in a disproportionate amount of a
20 substance which is most often abused going to a particular
21 geographic region where there was known diversion,
 - 22 2. orders that purchased a disproportionate amount of a
23 substance which is most often abused compared to other
24 products, and
 - 25 3. orders from downstream customers to distributors who
26 were purchasing from multiple different distributors, of
27 which Mallinckrodt was aware;
 - 28 iv. use "chargeback" information from its distributors to evaluate
suspicious orders. Chargebacks include downstream purchasing
information tied to certain discounts, providing Mallinckrodt
with data on buying patterns for Mallinckrodt products; and
 - v. take sufficient action to prevent recurrence of diversion by
downstream customers after receiving concrete information of
diversion of Mallinckrodt product by those downstream
customers.¹⁸⁶

318. Mallinckrodt agreed that its "system to monitor and detect suspicious
orders did not meet the standards outlined in letters from the DEA Deputy

¹⁸⁶ 2017 Mallinckrodt MOA at 2-3.

1 Administrator, Office of Diversion Control, to registrants dated September 27, 2006
 2 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the
 3 importance of the prevention of diversion of the controlled substances they
 4 manufacture” and would “design and operate a system that meets the requirements
 5 of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction
 6 information to identify suspicious orders of any Mallinckrodt product. Further,
 7 Mallinckrodt agrees to notify DEA of any diversion and/or suspicious
 8 circumstances involving any Mallinckrodt controlled substances that Mallinckrodt
 9 discovers.”¹⁸⁷

10 319. Mallinckrodt acknowledged that “[a]s part of their business model
 11 Mallinckrodt collects transaction information, referred to as chargeback data, from
 12 their direct customers (distributors). The transaction information contains data
 13 relating to the direct customer sales of controlled substances to ‘downstream’
 14 registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA
 15 when Mallinckrodt concludes that the chargeback data or other information
 16 indicates that a downstream registrant poses a risk of diversion.”¹⁸⁸

17 320. The same duties imposed by federal law on Mallinckrodt were
 18 imposed upon all Manufacturer Defendants.

19 321. The same business practices utilized by Mallinckrodt regarding
 20 “charge backs” and receipt and review of data from opioid distributors regarding
 21 orders of opioids were utilized industry-wide among opioid manufacturers and
 22 distributors, including, upon information and belief, the other Manufacturer
 23 Defendants.

24 322. Through, *inter alia*, the charge back data, the Manufacturer
 25 Defendants could monitor suspicious orders of opioids.

26
 27 _____
¹⁸⁷ *Id.* at 3-4.

28 ¹⁸⁸ *Id.* at 5.

1 323. The Manufacturer Defendants failed to monitor, report, and halt
2 suspicious orders of opioids as required by federal and state law.

3 324. The Manufacturer Defendants' failures to monitor, report, and halt
4 suspicious orders of opioids were intentional and unlawful.

5 325. The Manufacturer Defendants have misrepresented their compliance
6 with federal and state law.

7 326. The Manufacturer Defendants enabled the supply of prescription
8 opioids to obviously suspicious physicians and pharmacies, enabled the illegal
9 diversion of opioids, aided criminal activity, and disseminated massive quantities
10 of prescription opioids into the black market.

11 327. The wrongful actions and omissions of the Manufacturer Defendants
12 which have caused the diversion of opioids and which have been a substantial
13 contributing factor to and/or proximate cause of the opioid crisis are alleged in
14 greater detail in the racketeering allegations below.

15 328. The Manufacturer Defendants' actions and omissions in failing to
16 effectively prevent diversion and failing to monitor, report, and prevent suspicious
17 orders have enabled the unlawful diversion of opioids into Plaintiffs' Community.

18 **E. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF**
19 **LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND**
20 **SUBSTANTIAL DAMAGES.**

21 329. As the Manufacturer Defendants' efforts to expand the market for
22 opioids increased so have the rates of prescription and sale of their products — and
23 the rates of opioid-related substance abuse, hospitalization, and death among the
24 people of the State and the Plaintiffs' Community. The Distributor Defendants have
25 continued to unlawfully ship these massive quantities of opioids into communities
26 like the Plaintiffs' Community, fueling the epidemic.

1 330. There is a “parallel relationship between the availability of prescription
2 opioid analgesics through legitimate pharmacy channels and the diversion and
3 abuse of these drugs and associated adverse outcomes.”¹⁸⁹

4 331. Opioid analgesics are widely diverted and improperly used, and the
5 widespread use of the drugs has resulted in a national epidemic of opioid overdose
6 deaths and addictions.¹⁹⁰

7 332. The epidemic is “directly related to the increasingly widespread
8 misuse of powerful opioid pain medications.”¹⁹¹

9 333. The increased abuse of prescription painkillers along with growing
10 sales has contributed to a large number of overdoses and deaths.¹⁹²

11 334. As shown above, the opioid epidemic has escalated in Plaintiffs’
12 Community with devastating effects. Substantial opiate-related substance abuse,
13 hospitalization and death mirrors Defendants’ increased distribution of opiates.

14 335. Because of the well-established relationship between the use of
15 prescription opiates and the use of non-prescription opioids, like heroin, the massive
16 distribution of opioids to Plaintiffs’ Community and areas from which such opioids
17 are being diverted into Plaintiffs’ Community, has caused the Defendant-caused
18 opioid epidemic to include heroin addiction, abuse, and death.

19 336. Prescription opioid abuse, addiction, morbidity, and mortality are
20 hazards to public health and safety in the State and in Plaintiffs’ Community.

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22
23 ¹⁸⁹ See Richard C. Dart et al., Trends in Opioid Analgesic Abuse and Mortality in
24 the United States, 372 N. Eng. J. Med. 241 (2015).

25 ¹⁹⁰ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—*
Misconceptions and Mitigation Strategies, 374 N. Eng. J. Med. 1253 (2016).

26 ¹⁹¹ See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*,
374 N. Eng. J. Med. 1480 (2016).

27 ¹⁹² See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep’t of
28 Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels
(Nov. 1, 2011),
https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

1 337. Heroin abuse, addiction, morbidity, and mortality are hazards to public
2 health and safety in the State and in Plaintiffs' Community.

3 338. Defendants repeatedly and purposefully breached their duties under
4 state and federal law, and such breaches are direct and proximate causes of, and/or
5 substantial factors leading to, the widespread diversion of prescription opioids for
6 nonmedical purposes into the Plaintiffs' Community.

7 339. The unlawful diversion of prescription opioids is a direct and
8 proximate cause of, and/or substantial factor leading to, the opioid epidemic,
9 prescription opioid abuse, addiction, morbidity and mortality in the State and
10 Plaintiffs' Community. This diversion and the epidemic are direct causes of
11 foreseeable harms incurred by the Plaintiffs and Plaintiffs' Community.

12 340. Defendants' intentional and/or unlawful conduct resulted in direct and
13 foreseeable, past and continuing, economic damages for which Plaintiffs seek relief,
14 as alleged herein. Plaintiffs also seek the means to abate the epidemic created by
15 Defendants' wrongful and/or unlawful conduct.

16 341. The County seeks economic damages from the Defendants as
17 reimbursement for the costs associated with damage to its property and past efforts
18 to eliminate the hazards to public health and safety.

19 342. Plaintiffs seek economic damages from the Defendants to pay for the
20 cost to permanently eliminate the hazards to public health and safety and abate the
21 temporary public nuisance.

22 343. To eliminate the hazard to public health and safety, and abate the
23 public nuisance, a "multifaceted, collaborative public health and law enforcement
24 approach is urgently needed."¹⁹³

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28 ¹⁹³ See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016), at 1145.

1 344. A comprehensive response to this crisis must focus on preventing new
2 cases of opioid addiction, identifying early opioid-addicted individuals, and
3 ensuring access to effective opioid addiction treatment while safely meeting the
4 needs of patients experiencing pain.¹⁹⁴

5 345. These community-based problems require community-based solutions
6 that have been limited by “budgetary constraints at the state and Federal levels.”¹⁹⁵

7 346. Having profited enormously through the aggressive sale, misleading
8 promotion, and irresponsible distribution of opiates, Defendants should be required
9 to take responsibility for the financial burdens their conduct has inflicted upon the
10 Plaintiffs and Plaintiffs’ Community.

11 **F. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS**
12 **ARE ESTOPPED FROM ASSERTING STATUTES OF**
13 **LIMITATIONS AS DEFENSES.**

14 **1. Enforcement of a Public Right.**

15 347. No statute of limitation can be pleaded against the Plaintiffs, which
16 seek to enforce strictly public rights.

17 **2. Continuing Conduct.**

18 348. Plaintiffs contend they continue to suffer harm from the unlawful
19 actions by the Defendants.

20 349. The continued tortious and unlawful conduct by the Defendants causes
21 a repeated or continuous injury. The damages have not occurred all at once but
22 have continued to occur and have increased as time progresses. The tort is not
23

24
25 ¹⁹⁴ See Johns Hopkins Bloomberg School of Public Health, *The Prescription*
26 *Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds.,
27 2015), [http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-](http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf)
28 [and-effectiveness/research/prescription-](http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf)
[opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf](http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf).

¹⁹⁵ See Office of Nat’l Drug Control Policy, Exec. Office of the President,
Epidemic: Responding to America’s Prescription Drug Abuse Crisis (2011),
https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

1 completed nor have all the damages been incurred until the wrongdoing ceases. The
 2 wrongdoing and unlawful activity by Defendants has not ceased. The public
 3 nuisance remains unabated. The conduct causing the damages remains unabated.

4 **3. Equitable Estoppel.**

5 350. To the extent any statute of limitations defense would apply,
 6 Defendants are equitably estopped from relying upon a statute of limitations
 7 defense because they undertook active efforts to deceive Plaintiffs and to
 8 purposefully conceal their unlawful conduct and fraudulently assure the public,
 9 including the State, the Plaintiffs, and Plaintiffs' Community, that they were
 10 undertaking efforts to comply with their obligations under the state and federal
 11 controlled substances laws, all with the goal of protecting their registered
 12 manufacturer or distributor status in the State and to continue generating profits.
 13 Notwithstanding the allegations set forth above, the Defendants affirmatively
 14 assured the public, including the State, the Plaintiffs, and Plaintiffs' Community,
 15 that they are working to curb the opioid epidemic.

16 351. For example, a Cardinal Health executive claimed that it uses
 17 "advanced analytics" to monitor its supply chain, and assured the public it was
 18 being "as effective and efficient as possible in constantly monitoring, identifying,
 19 and eliminating any outside criminal activity."¹⁹⁶

20 352. Similarly, McKesson publicly stated that it has a "best-in-class
 21 controlled substance monitoring program to help identify suspicious orders," and
 22 claimed it is "deeply passionate about curbing the opioid epidemic in our
 23 country."¹⁹⁷

24
 25 ¹⁹⁶ Bernstein et al., *supra*.

26 ¹⁹⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as*
 27 *the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016,
 28 https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

1 353. Moreover, in furtherance of their effort to affirmatively conceal their
 2 conduct and avoid detection, the Distributor Defendants, through their trade
 3 associations, HDMA and NACDS, filed an *amicus* brief in *Masters*
 4 *Pharmaceuticals*, which made the following statements:¹⁹⁸

- 5 a. “HDMA and NACDS members not only have statutory and regulatory
 6 responsibilities to guard against diversion of controlled prescription
 7 drugs, but undertake such efforts as responsible members of society.”
- 8 b. “DEA regulations that have been in place for more than 40 years
 9 require distributors to *report* suspicious orders of controlled
 10 substances to DEA based on information readily available to them
 11 (e.g., a pharmacy’s placement of unusually frequent or large orders).”
- 12 c. “Distributors take seriously their duty to report suspicious orders,
 13 utilizing both computer algorithms and human review to detect
 14 suspicious orders based on the generalized information that *is* available
 15 to them in the ordering process.”
- 16 d. “A particular order or series of orders can raise red flags because of its
 17 unusual size, frequency, or departure from typical patterns with a given
 18 pharmacy.”
- 19 e. “Distributors also monitor for and report abnormal behavior by
 20 pharmacies placing orders, such as refusing to provide business
 21 contact information or insisting on paying in cash.”

22 Through the above statements made on their behalf by their trade associations, and
 23 other similar statements assuring their continued compliance with their legal
 24 obligations, the Distributor Defendants not only acknowledged that they understood
 25 their obligations under the law, but they further affirmed that their conduct was in
 26 compliance with those obligations.

27 354. The Distributor Defendants have also concealed and prevented
 28 discovery of information, including data from the ARCOS database that will
 confirm their identities and the extent of their wrongful and illegal activities.

355. The Manufacturer Defendants distorted the meaning or import of
 studies they cited and offered them as evidence for propositions the studies did not
 support. The Manufacturer Defendants invented “pseudoaddiction” and promoted

¹⁹⁸ Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

1 it to an unsuspecting medical community. The Manufacturer Defendants provided
 2 the medical community with false and misleading information about ineffectual
 3 strategies to avoid or control opioid addiction. The Manufacturer Defendants
 4 recommended to the medical community that dosages be increased, without
 5 disclosing the risks. The Manufacturer Defendants spent millions of dollars over a
 6 period of years on a misinformation campaign aimed at highlighting opioids'
 7 alleged benefits, disguising the risks, and promoting sales. The medical community,
 8 consumers, the State, and Plaintiffs' Community were duped by the Manufacturer
 9 Defendants' campaign to misrepresent and conceal the truth about the opioid drugs
 10 that they were aggressively pushing in the State and in Plaintiffs' Community.

11 356. Defendants intended that their actions and omissions would be relied
 12 upon, including by Plaintiffs and Plaintiffs' Community. Plaintiffs and Plaintiffs'
 13 Community did not know, and did not have the means to know, the truth due to
 14 Defendants' actions and omissions.

15 357. The Plaintiffs and Plaintiffs' Community reasonably relied on
 16 Defendants' affirmative statements regarding their purported compliance with their
 17 obligations under the law and consent orders. To the extent statutes of limitations
 18 could apply to Plaintiffs' claims, Plaintiffs failed to commence an action within the
 19 statutory periods because of reliance on Defendants' wrongful conduct.

20 358. Defendants are estopped from asserting a statute of limitations defense
 21 because their conduct and misrepresentations were so unfair and misleading as to
 22 outweigh the public's interest in setting limitations on bringing actions.

23 **4. Fraudulent Concealment**

24 359. To the extent any statute of limitations defense would apply, Plaintiffs'
 25 claims are further subject to equitable tolling, stemming from Defendants' knowing
 26 and fraudulent concealment of the facts alleged herein. As alleged herein,
 27 Defendants knew of the wrongful acts set forth above, had material information
 28 pertinent to their discovery, and concealed them from the Plaintiffs and Plaintiffs'

1 Community. The Plaintiffs did not know, or could not have known through the
2 exercise of reasonable diligence, of their causes of action, as a result of Defendants'
3 conduct.

4 360. The purposes of the statutes of limitations period, if any, are satisfied
5 because Defendants cannot claim prejudice due to a late filing where the Plaintiffs
6 filed suit promptly upon discovering the facts essential to their claims, described
7 herein, which Defendants knowingly concealed.

8 361. In light of their statements to the media, in legal filings and in
9 settlements, it is clear that Defendants had actual or constructive knowledge that
10 their conduct was deceptive, in that they consciously concealed the schemes set
11 forth herein.

12 362. Defendants continually and secretly engaged in their scheme to avoid
13 compliance with their legal obligations. Only Defendants and their agents knew or
14 could have known about Defendants' unlawful actions because Defendants made
15 deliberate efforts to conceal their conduct. As a result of the above, the Plaintiffs
16 were unable to obtain vital information bearing on their claims absent any fault or
17 lack of diligence on their part.

18 **V. LEGAL CAUSES OF ACTION**

19 **COUNT I**

20 **PUBLIC NUISANCE**

21 **(Brought by The People Against all Defendants)**

22 363. Plaintiff, The People, incorporate by reference all other paragraphs of
23 this Complaint as if fully set forth here, and further allege as follows.

24 364. Each Defendant is liable for public nuisance because its conduct at
25 issue has caused an unreasonable and substantial interference with a right common
26 to the general public. *See Cty. of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App.
27 4th 292, 305, 40 Cal. Rptr. 3d 313, 325 (2006) (cit. om.). The interference is
28 substantial "if it causes significant harm and unreasonable if its social utility is

1 outweighed by the gravity of the harm inflicted.” *Id.* The causation element of a
2 public nuisance cause of action is satisfied if the defendant’s conduct is a substantial
3 factor in bringing about the result. *People v. Conagra Grocery Prod. Co.*, 17 Cal.
4 App. 5th 51, 101-02, 227 Cal. Rptr. 3d 499, 543 (Ct. App. 2017), *reh'g denied* (Dec.
5 6, 2017), *review denied* (Feb. 14, 2018).

6 365. Under California law, a nuisance is “anything which is injurious to
7 health, including but not limited to the illegal sale of controlled substances, or is
8 indecent or offensive to the senses, or an obstruction to the free use of property, so
9 as to interfere with the comfortable enjoyment of life or property.” Cal. Civ. Code
10 § 3479.

11 366. California defines a “public nuisance” as “one which affects at the
12 same time an entire community or neighborhood, or any considerable number of
13 persons, although the extent of the annoyance or damage inflicted upon individuals
14 may be unequal.” Cal. Civ. Code § 3480.

15 367. Defendants have created a public nuisance under California law.

16 368. The People have standing to bring this claim to abate the public
17 nuisance due to the opioid epidemic which was created by Defendants and which is
18 affecting and causing harm in Plaintiffs’ Community. *See* Cal. Civ. Proc. Code §
19 731.

20 369. By causing dangerously addictive drugs to flood the community, and
21 to be diverted for illicit purposes, in contravention of federal and state law, each
22 Defendant has injuriously affected rights common to the general public, specifically
23 including the rights of the people of the Plaintiffs’ Community to public health,
24 public safety, public peace, public comfort, and public convenience. The public
25 nuisance caused by Defendants’ diversion of dangerous drugs has caused
26 substantial annoyance, inconvenience, and injury to the public.

27 370. By selling dangerously addictive opioid drugs diverted from a
28 legitimate medical, scientific, or industrial purpose, Defendants have committed a

1 course of conduct that injuriously affects the safety, health, and morals of the people
2 of the Plaintiffs' Community.

3 371. By failing to maintain a closed system that guards against diversion of
4 dangerously addictive drugs for illicit purposes, Defendants injuriously affected
5 public rights, including the right to public health, public safety, public peace, and
6 public comfort of the people of the Plaintiffs' Community.

7 372. By affirmatively promoting opioids for use for chronic pain,
8 affirmatively promoting opioids as not addictive, affirmatively fostering a
9 misunderstanding of the signs of addiction and how to reliably identify and safely
10 prescribe opioids to patients predisposed to addiction, affirmatively exaggerating
11 the risks of competing medications like NSAIDs, affirmatively promoting their so-
12 called abuse-deterrent opioid formulations and affirmatively identifying and
13 targeting susceptible prescribers and vulnerable patient populations, Defendants
14 injuriously affected public rights, including the right to public health, public safety,
15 public peace, and public comfort of the people of the Plaintiffs' Community. The
16 public nuisance caused by Defendants' affirmative promotion of opioids has caused
17 substantial annoyance, inconvenience, and injury to the public.

18 373. Defendants' interference with the comfortable enjoyment of life in the
19 Plaintiffs' Community is unreasonable because there is little social utility to opioid
20 diversion and abuse, and any potential value is outweighed by the gravity of the
21 harm inflicted by Defendants' actions.

22 374. The People allege that Defendants' wrongful and illegal actions have
23 created a public nuisance. Each Defendant is liable for public nuisance because its
24 conduct at issue has caused an unreasonable and substantial interference with a right
25 common to the general public.

26 375. The Defendants have intentionally and/or unlawfully created a
27 nuisance.
28

1 376. The residents of Plaintiffs' Community have a common right to be free
2 from conduct that creates an unreasonable jeopardy to the public health, welfare
3 and safety, and to be free from conduct that creates a disturbance and reasonable
4 apprehension of danger to person and property.

5 377. Defendants intentionally, unlawfully, and recklessly manufacture,
6 market, distribute, promote and sell prescription opioids that Defendants know, or
7 reasonably should know, will be diverted, causing widespread distribution of
8 prescription opioids in and/or to Plaintiffs' Community, resulting in addiction and
9 abuse, an elevated level of crime, death and injuries to the residents of Plaintiffs'
10 Community, a higher level of fear, discomfort and inconvenience to the residents
11 of Plaintiffs' Community, and direct costs to Plaintiffs' Community.

12 378. Defendants have unlawfully and/or intentionally caused and permitted
13 dangerous drugs under their control to be diverted such as to injure the Plaintiffs'
14 Community and its residents.

15 379. Defendants have unlawfully and/or intentionally promoted and
16 distributed opioids or caused opioids to be distributed without maintaining effective
17 controls against diversion. Such conduct was illegal. Defendants' failures to
18 maintain effective controls against diversion include Defendants' failure to
19 effectively monitor for suspicious orders, report suspicious orders, and/or stop
20 shipment of suspicious orders.

21 380. Defendants have caused a significant and unreasonable interference
22 with the public health, safety, welfare, peace, comfort and convenience, and ability
23 to be free from disturbance and reasonable apprehension of danger to person or
24 property.

25 381. Defendants' conduct in illegally distributing and selling prescription
26 opioids, or causing such opioids to be distributed and sold, where Defendants know,
27 or reasonably should know, such opioids will be diverted and possessed and/or used
28 illegally in Plaintiffs' Community is of a continuing nature.

1 382. Defendants' actions have been of a continuing nature and have
2 produced a significant effect upon the public's rights, including the public's right
3 to health and safety.

4 383. A violation of any rule or law controlling the distribution of a drug of
5 abuse in Plaintiffs' Community and the State is a public nuisance.

6 384. Defendants' distribution of opioids while failing to maintain effective
7 controls against diversion was proscribed by statute and regulation.

8 385. Defendants' ongoing conduct produces an ongoing nuisance, as the
9 prescription opioids that they allow and/or cause to be illegally distributed and
10 possessed in Plaintiffs' Community will be diverted, leading to abuse, addiction,
11 crime, and public health costs.

12 386. Because of the continued use and addiction caused by these illegally
13 distributed opioids, The People will continue to fear for their health, safety and
14 welfare, and will be subjected to conduct that creates a disturbance and reasonable
15 apprehension of danger to person and property.

16 387. Defendants know, or reasonably should know, that their conduct will
17 have an ongoing detrimental effect upon the public health, safety and welfare, and
18 the public's ability to be free from disturbance and reasonable apprehension of
19 danger to person and property.

20 388. Defendants know, or reasonably should know, that their conduct
21 causes an unreasonable and substantial invasion of the public right to health, safety
22 and welfare and the public's ability to be free from disturbance and reasonable
23 apprehension of danger to person and property.

24 389. Defendants are aware, and at a bare minimum certainly should be
25 aware, of the unreasonable interference that their conduct has caused in Plaintiffs'
26 Community. Defendants are in the business of manufacturing, marketing, selling,
27 and distributing prescription drugs, including opioids, which are specifically known
28 to Defendants to be dangerous because *inter alia* these drugs are defined under

1 federal and state law as substances posing a high potential for abuse and severe
2 addiction. *See, e.g.*, 21 U.S.C. § 812 (b)(2). Defendants created an intentional
3 nuisance. Defendants' actions created and expanded the abuse of opioids, drugs
4 specifically codified as constituting severely harmful substances.

5 390. Defendants' conduct in promoting, marketing, distributing, and selling
6 prescription opioids which the Defendants know, or reasonably should know, will
7 likely be diverted for non-legitimate, non-medical use, creates a strong likelihood
8 that these illegal distributions of opioids will cause death and injuries to residents
9 in Plaintiffs' Community and otherwise significantly and unreasonably interfere
10 with public health, safety and welfare, and with The People's right to be free from
11 disturbance and reasonable apprehension of danger to person and property.

12 391. It is, or should be, reasonably foreseeable to defendants that their
13 conduct will cause deaths and injuries to residents in Plaintiffs' Community, and
14 will otherwise significantly and unreasonably interfere with public health, safety
15 and welfare, and with the public's right to be free from disturbance and reasonable
16 apprehension of danger to person and property.

17 392. The prevalence and availability of diverted prescription opioids in the
18 hands of irresponsible persons and persons with criminal purposes in Plaintiffs'
19 Community not only causes deaths and injuries, but also creates a palpable climate
20 of fear among residents in Plaintiffs' Community where opioid diversion, abuse,
21 addiction are prevalent and where diverted opioids tend to be used frequently.

22 393. Defendants' conduct makes it easier for persons to divert prescription
23 opioids, constituting a dangerous threat to the public.

24 394. Defendants' actions were, at the least, a substantial factor in opioids
25 becoming widely available and widely used for non-medical purposes. Because of
26 Defendants' affirmative promotion of opioids and special positions within the
27 closed system of opioid distribution, without Defendants' actions, opioid use would
28 not have become so widespread, and the enormous public health hazard of

1 prescription opioid and heroin overuse, abuse, and addiction that now exists would
2 have been averted.

3 395. The presence of diverted prescription opioids in Plaintiffs'
4 Community, and the consequence of prescription opioids having been diverted in
5 Plaintiffs' Community, proximately results in and/or substantially contributes to the
6 creation of significant future costs to The People and to Plaintiffs' Community in
7 order to enforce the law, equip its police force and treat the victims of opioid abuse
8 and addiction.

9 396. Stemming the flow of illegally distributed prescription opioids, and
10 abating the nuisance caused by the illegal flow of opioids, will help to alleviate this
11 problem, save lives, prevent injuries and make Plaintiffs' Community a safer place
12 to live.

13 397. Defendants' conduct is a direct and proximate cause of and/or a
14 substantial contributing factor to opioid addiction and abuse in Plaintiffs'
15 Community, costs that will be borne by Plaintiffs' Community and The People, and
16 a significant and unreasonable interference with public health, safety and welfare,
17 and with the public's right to be free from disturbance and reasonable apprehension
18 of danger to person and property.

19 398. Defendants' conduct constitutes a public nuisance and, if unabated,
20 will continue to threaten the health, safety and welfare of the residents of Plaintiffs'
21 Community, creating an atmosphere of fear and addiction that tears at the residents'
22 sense of well-being and security. The People have a clearly ascertainable right to
23 prospectively abate conduct that perpetuates this nuisance.

24 399. Defendants created an intentional nuisance. Defendants' actions
25 created and expanded the abuse of opioids, which are dangerously addictive, and
26 the ensuing associated plague of prescription opioid and heroin addiction.
27 Defendants knew the dangers to public health and safety that diversion of opioids
28 would create in Plaintiffs' Community; however, Defendants intentionally and/or

1 unlawfully failed to maintain effective controls against diversion through proper
2 monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants
3 intentionally and/or unlawfully distributed opioids or caused opioids to be
4 distributed without reporting or refusing to fill suspicious orders or taking other
5 measures to maintain effective controls against diversion. Defendants intentionally
6 and/or unlawfully continued to ship and failed to halt suspicious orders of opioids,
7 or caused such orders to be shipped. Defendants intentionally and/or unlawfully
8 promoted and marketed opioids in manners they knew to be false and misleading.
9 Such actions were inherently dangerous.

10 400. Defendants knew the prescription opioids have a high likelihood of
11 being diverted. It was foreseeable to Defendants that where Defendants distributed
12 prescription opioids or caused such opioids to be distributed without maintaining
13 effective controls against diversion, including monitoring, reporting, and refusing
14 shipment of suspicious orders, that the opioids would be diverted, and create an
15 opioid abuse nuisance in Plaintiffs' Community.

16 401. Defendants' actions also created a nuisance by acting recklessly,
17 negligently and/or carelessly, in breach of their duties to maintain effective controls
18 against diversion, thereby creating an unreasonable and substantial risk of harm.

19 402. Defendants acted with actual malice because Defendants acted with a
20 conscious disregard for the rights and safety of other persons, and said actions have
21 a great probability of causing substantial harm.

22 403. The public nuisance created, perpetuated and maintained by
23 Defendants can be prospectively abated and further reoccurrence of such harm and
24 inconvenience can be prevented.

25 404. The People further seek to prospectively abate the nuisance created by
26 the Defendants' unreasonable, unlawful, intentional, ongoing, continuing,
27 substantial and persistent actions and omissions and interference with a right
28 common to the public.

1 405. Defendants' intentional and unlawful actions and omissions and
2 unreasonable interference with a right common to the public are of a continuing
3 nature.

4 406. The public nuisance created by Defendants' actions is substantial and
5 unreasonable – it has caused and continues to cause significant harm to the
6 community, and the harm inflicted outweighs any offsetting benefit. The staggering
7 rates of opioid and heroin use resulting from the Defendants' abdication of their
8 gate-keeping and diversion prevention duties, and the Manufacturer Defendants'
9 fraudulent marketing activities, have caused harm to the entire community that
10 includes, but is not limited to the following:

- 11 a. The high rates of use leading to unnecessary opioid abuse, addiction,
12 overdose, injuries, and deaths.
- 13 b. Even children have fallen victim to the opioid epidemic. Easy access
14 to prescription opioids made opioids a recreational drug of choice
15 among teenagers. Even infants have been born addicted to opioids due
16 to prenatal exposure, causing severe withdrawal symptoms and lasting
17 developmental impacts.
- 18 c. Even those residents of Plaintiffs' Community who have never taken
19 opioids have suffered from the public nuisance arising from
20 Defendants' abdication of their gate-keeper duties and fraudulent
21 promotions. Many residents have endured and will endure both the
22 emotional and financial costs of caring for loved ones addicted to or
23 injured by opioids, and the loss of companionship, wages, or other
24 support from family members who have used, abused, become
25 addicted to, overdosed on, or been killed by opioids.
- 26 d. The opioid epidemic has increased and will increase health care costs.
- 27 e. Employers have lost and will continue to lose the value of productive
28 and healthy employees.
- f. Defendants' conduct created and continues to create an abundance of
drugs available for criminal use and fueled a new wave of addiction,
abuse, and injury.
- g. Defendants' dereliction of duties and/or fraudulent misinformation
campaign pushing dangerous drugs resulted in a diverted supply of
narcotics to sell, and the ensuing demand of addicts to buy them. More
prescription opioids sold by Defendants led to more addiction, with
many addicts turning from prescription opioids to heroin. People
addicted to opioids frequently require increasing levels of opioids, and
many are turning to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids has increased and continues to increase the demands on health care services and law enforcement.

- i. The significant and unreasonable interference with the public rights caused by Defendants' conduct has taxed and continues to tax the human, medical, public health, law enforcement, and financial resources of the Plaintiffs' Community.

407. The People seek all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief and expenses to prospectively abate the nuisance.

408. Pursuant to California Code of Civil Procedure section 731, The People request an order from the Court on behalf of The People providing for abatement of Defendants' ongoing violations of California Civil Code Sections 3479 and 3480, and enjoining Defendants from future violations of California Civil Code Sections 3479 and 3480.

409. Each Defendant created or assisted in the creation of the epidemic of opioid use and injury and each Defendant is jointly and severally liable for abating it.

COUNT II

PUBLIC NUISANCE

(Brought by The County Against all Defendants)

410. Plaintiff, The County, incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

411. As set forth above, each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public. *See, e.g., Cty. of Santa Clara v. Atl. Richfield Co.*, 137 Cal. App. 4th 292, 305, 40 Cal. Rptr. 3d 313, 325 (2006); Cal. Civ. Code §§ 3479; 3480.

412. Defendants have created a public nuisance under California law.

1 413. The County has standing to bring this claim for damages incurred to
 2 its property by the public nuisance due to the opioid epidemic which was created
 3 by Defendants and which is affecting and causing harm to The County. An action
 4 can be “brought by any person whose property is injuriously affected, or whose
 5 personal enjoyment is lessened by a nuisance, as defined in Section 3479 of the
 6 Civil Code, and by the judgment in that action the nuisance may be enjoined or
 7 abated as well as damages recovered therefor.” Cal. Civ. Proc. Code § 731. “Where
 8 a public entity can show it has a property interest injuriously affected by the
 9 nuisance, then, like any other such property holder, it should be able to pursue the
 10 full panoply of tort remedies available to private persons.” *Selma Pressure Treating*
 11 *Co. v. Osmose Wood Preserving Co.*, 221 Cal. App. 3d 1601, 1616, 271 Cal. Rptr.
 12 596, 604 (Ct. App. 1990).

13 414. The County has suffered harm to its property interests that is different
 14 from the type of harm suffered by the general public and has incurred substantial
 15 costs deriving from having to replace and retrofit its property that has been damaged
 16 and is being damaged by Defendants’ intentional, unlawful, and reckless
 17 manufacturing, marketing, distribution, promotion and sale of prescription opioids.

18 415. Defendants intentionally, unlawfully, and recklessly manufacture,
 19 market, distribute, promote and sell prescription opioids that Defendants know, or
 20 reasonably should know, will be diverted, causing widespread distribution of
 21 prescription opioids in and/or to Plaintiffs’ Community, resulting in The County
 22 having to repair and remake its infrastructure, property and systems that have been
 23 damaged by Defendants’ action, including, *inter alia*, its property and systems to
 24 treat addiction and abuse, to respond to and manage an elevated level of
 25 emergencies and crime, and to respond to and treat injuries and process deaths in
 26 Plaintiffs’ Community.

27 416. The County owns property which has been injuriously affected by the
 28 public nuisance caused by Defendants. These property interests, include, *inter alia*,

1 additional naloxone doses – The County owns these doses which have been and are
2 destroyed when The County has to administer them to persons who are overdosing
3 as a result of Defendants’ intentional, unlawful, and reckless manufacturing,
4 marketing, distribution, promotion and sale of prescription opioids. The County’s
5 emergency response system and medical services equipment and other materials
6 will similarly need to be improved and replaced because this property has been and
7 is being damaged due to persons who are overdosing as a result of Defendants’
8 intentional, unlawful, and reckless manufacturing, marketing, distribution,
9 promotion and sale of prescription opioids. The County also has damage to its
10 property related to evidence gathering and testing for the prosecution of drug related
11 crimes.

12 417. In addition, The County has suffered damages to its infrastructure,
13 which will need to be retrofitted and repaired as a result of Defendants’ intentional,
14 unlawful, and reckless manufacturing, marketing, distribution, promotion and sale
15 of prescription opioids. This damage includes damage to its law enforcement,
16 medical and rehabilitation infrastructures and systems which are now inadequate to
17 handle the new undue burden on these systems caused by Defendants’ conduct. This
18 includes, *inter alia*, repairing and upgrading jail facilities to add additional jail space
19 and beds for opioid addicts who commit crimes as well as retrofitting the facilities
20 to treat inmates’ addictions. This also includes repairing and upgrading court
21 systems for prosecution and defense of drug-related crimes. This also includes
22 repairing and upgrading hospital and treatment facilities for members of Plaintiffs’
23 Community addicted to opioids as well as property that is part of and used by The
24 County’s Department of the Medical Examiner which must investigate deaths
25 known or suspected to be due to drug intoxication.

26 418. The County owns, operates, manages, maintains, and otherwise has
27 property interests in, all of which have been injured, damaged, or affected by
28 Defendants, the following property:

- a. County Jail system, including buildings, cells, beds, supplies, resources, materials, personnel, equipment, and other property.
- b. County Probation system, including offices, personnel, supplies, resources, materials, equipment, and other property.
- c. County District Attorney system, including offices, personnel, supplies, resources, materials, equipment, and other property.
- d. County Health and Human Services system, including offices, personnel, supplies, resources, materials, equipment, and other property.
- e. County Sheriff and Law Enforcement systems, including Narcan, naloxone, offices, personnel, supplies, resources, materials, equipment, and other property.
- f. County Public Health system, including offices, personnel, resources, supplies, equipment, materials, and other property.

419. As set forth above in allegations specifically incorporated herein, by selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific, or industrial purpose, Defendants have committed a course of conduct that injuriously affects The County and its property.

420. The public nuisance caused by Defendants' affirmative promotion of opioids has caused substantial annoyance, inconvenience, and injury to The County and The County's property.

421. The acts by Defendants which have injured The County and its property are unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

422. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the County's property.

1 423. Defendants' conduct in illegally distributing and selling prescription
2 opioids, or causing such opioids to be distributed and sold, where Defendants know,
3 or reasonably should know, such opioids will be diverted and possessed and/or used
4 illegally in Plaintiffs' Community is of a continuing nature and has produced a
5 significant injury to The County and its property.

6 424. Defendants' ongoing conduct produces an ongoing nuisance.

7 425. Defendants know, or reasonably should know, that their conduct will
8 have an ongoing detrimental effect upon The County and The County's property.

9 426. Defendants' actions were, at the least, a substantial factor causing the
10 harm to The County and its property.

11 427. The presence of diverted prescription opioids in Plaintiffs'
12 Community, and the consequence of prescription opioids having been diverted in
13 Plaintiffs' Community, proximately results in and/or substantially contributes to the
14 creation of significant past and future costs to The County as it must repair and
15 retrofit its property in order to enforce the law and treat the victims of opioid abuse
16 and addiction.

17 428. Defendants' conduct is a direct and proximate cause of and/or a
18 substantial contributing factor to opioid addiction and abuse in Plaintiffs'
19 Community, costs that will be borne by Plaintiffs' Community and The County.

20 429. As a direct and proximate result of Defendants' creation of a public
21 nuisance, The County has suffered and continues to suffer damages to its property
22 requiring investigation, repair, remediation, and other costs to be determined at trial.

23 430. The damages available to The County include, *inter alia*, recoupment
24 of governmental costs, flowing from the damages to The County's property which
25 The County seeks to recover damages for. Defendants' conduct is ongoing and
26 persistent, and The County seeks all damages flowing from Defendants' conduct.

27 431. As a direct result of Defendants' conduct, The County and Plaintiffs'
28 Community have suffered actual injury and damages including, but not limited to,

1 significant expenses for repairing and retrofitting property related to police,
2 emergency, health, prosecution, corrections and other services. The County here
3 seeks recovery for its own harm.

4 432. The County has sustained specific and special injuries because its
5 damages include, *inter alia*, injury to the property and systems of its health services,
6 law enforcement, and medical examiner, as well as property costs related to opioid
7 addiction treatment and overdose prevention, as described in this Complaint.

8 433. The County seeks all legal and equitable relief as allowed by law,
9 including *inter alia* compensatory damages, from the Defendants for the creation of
10 a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

11 **COUNT III**

12 **RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT**

13 **18 U.S.C. § 1961, et seq.**

14 **(Against Defendants Purdue, Cephalon, Janssen, and Endo)**

15 **(The “Opioid Marketing Enterprise”)**

16 434. Plaintiff, The County, incorporates by reference all other paragraphs
17 of this Complaint as if fully set forth herein, and further alleges as follows.

18 435. Plaintiff, The County, brings this Count on behalf of itself against the
19 following Defendants, as defined above: Purdue, Cephalon, Janssen, and Endo
20 (referred to collectively for this Claim as the “RICO Marketing Defendants”).

21 436. At all relevant times, the RICO Marketing Defendants were and are
22 “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding,
23 and do hold, “a legal or beneficial interest in property.”

24 437. Section 1962(c) of RICO makes it unlawful “for any person employed
25 by or associated with any enterprise engaged in, or the activities of which affect,
26 interstate or foreign commerce, to conduct or participate, directly or indirectly, in
27 the conduct of such enterprise’s affairs through a pattern of racketeering activity.”
28 18 U.S.C. § 1962(c).

1 438. The term “enterprise” is defined as including “any individual,
2 partnership, corporation, association, or other legal entity, and any union or group
3 of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4).
4 The definition of “enterprise” in Section 1961(4) includes legitimate and
5 illegitimate enterprises within its scope. Specifically, the section “describes two
6 separate categories of associations that come within the purview of an ‘enterprise’
7 -- the first encompassing organizations such as corporations, partnerships, and other
8 ‘legal entities,’ and the second covering ‘any union or group of individuals
9 associated in fact although not a legal entity.’” *United State v. Turkette*, 452 U.S.
10 576, 577 (1981).

11 439. Beginning in the early 1990s, the RICO Marketing Defendants
12 aggressively sought to bolster their revenue, increase profit, and grow their share of
13 the prescription painkiller market by unlawfully increasing the volume of opioids
14 they sold. The RICO Marketing Defendants knew that they could not increase their
15 profits without misrepresenting that opioids were non-addictive and safe for the
16 long-term treatment of chronic pain.

17 440. The generally accepted standards of medical practice prior to the 1990s
18 dictated that opioids should only be used in short durations to treat acute pain, pain
19 relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due
20 to the evidence of addiction and lack of evidence indicating that opioids improved
21 patients’ ability to overcome pain and function, the use of opioids for chronic pain
22 was discouraged or prohibited. As a result, doctors generally did not prescribe
23 opioids for chronic pain.

24 441. Knowing that their products were highly addictive, ineffective and
25 unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain,
26 the RICO Marketing Defendants formed an association-in-fact enterprise and
27 engaged in a scheme to unlawfully increase their profits and sales, and grow their
28 share of the prescription painkiller market, through repeated and systematic

1 misrepresentations about the safety and efficacy of opioids for treating long-term
2 chronic pain.

3 442. The RICO Marketing Defendants formed an association-in-fact
4 enterprise consisting of “advocacy groups and professional societies” (“Front
5 Groups”) and paid “physicians affiliated with these groups” (KOLs”) in order to
6 unlawfully increase the demand for opioids. Through their personal relationships,
7 the RICO Marketing Defendants and members of the Opioid Marketing Enterprise
8 had the opportunity to form and take actions in furtherance of the Opioid Marketing
9 Enterprise’s common purpose. The RICO Marketing Defendants’ substantial
10 financial contribution to the Opioid Marketing Enterprise, and the advancement of
11 opioids-friendly messaging, fueled the U.S. opioids epidemic.¹⁹⁹

12 443. The RICO Marketing Defendants, through the Opioid Marketing
13 Enterprise, made misleading statements and misrepresentations about opioids that
14 downplayed the risk of addiction and exaggerated the benefits of opioid use,
15 including: (1) downplaying the serious risk of addiction; (2) creating and promoting
16 the concept of “pseudoaddiction” when signs of actual addiction began appearing
17 and advocated that the signs of addiction should be treated with more opioids; (3)
18 exaggerating the effectiveness of screening tools to prevent addiction; (4) claiming
19 that opioid dependence and withdrawal are easily managed; (5) denying the risks of
20 higher opioid dosages; and (6) exaggerating the effectiveness of “abuse-deterrent”
21 opioid formulations to prevent abuse and addiction.

22 444. The RICO Marketing Defendants also falsely touted the benefits of
23 long-term opioid use, including the supposed ability of opioids to improve function
24 and quality of life, even though there was no scientifically reliable evidence to
25 support the RICO Marketing Defendants’ claims.

26
27 ¹⁹⁹ *Fueling an Epidemic: Exposing the Financial Ties Between Opioid*
28 *Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security
& Governmental Affairs Committee, Ranking Members’ Office, February 12,
2018 <https://www.hsdl.org/?abstract&did=808171> (“*Fueling an Epidemic*”), at 1.

1 445. The RICO Marketing Defendants’ scheme, and the common purpose
 2 of the Opioid Marketing Enterprise, has been wildly successful. Opioids are now
 3 the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in
 4 revenue for drug companies in 2010 alone; sales in the United States have exceeded
 5 \$8 billion in revenue annually since 2009.²⁰⁰ In an open letter to the nation’s
 6 physicians in August 2016, the then-U.S. Surgeon General expressly connected this
 7 “urgent health crisis” to “heavy marketing of opioids to doctors . . . [m]any of
 8 [whom] were even taught – incorrectly – that opioids are not addictive when
 9 prescribed for legitimate pain.”²⁰¹

10 446. The scheme devised and implemented by the RICO Marketing
 11 Defendants amounted to a common course of conduct designed to ensure that the
 12 RICO Marketing Defendants unlawfully increased their sales and profits through
 13 misrepresentations about the addictive nature and effective use of the RICO
 14 Marketing Defendants’ drugs. As Senator McCaskill aptly recognized:

15 The opioid epidemic is the direct result of a calculated marketing and
 16 sales strategy developed in the 90’s, which delivered three simple
 17 messages to physicians. First, that chronic pain was severely
 18 undertreated in the United States. Second, that opioids were the best
 19 tool to address that pain. And third, that opioids could treat pain
 20 without risk of serious addiction. As it turns out, these messages were
 21 exaggerations at best and outright lies at worst.²⁰²

19 **A. THE OPIOID MARKETING ENTERPRISE**

20 447. The Opioid Marketing Enterprise consists of the RICO Marketing
 21 Defendants, the Front Groups, and the KOLs – each of whom is identified below:

23 ²⁰⁰ See Katherine Eban, *OxyContin: Purdue Pharma’s Painful Medicine*, Fortune,
 24 Nov. 9, 2011, [http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-](http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/)
 25 [medicine/](http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/); David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, Fin. Times,
 26 Aug. 10, 2016, [https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-](https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95)
 27 [a121aa8abd95](https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95).

26 ²⁰¹ Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016),
 27 <http://turnthetidex.org/>; *Fueling An Epidemic*, *supra* n.3, at 1.

28 ²⁰² See, *LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable*,
 September 12, 2017, at 31:03-31:37,
https://www.youtube.com/watch?v=k9mrQa8_vAo (accessed on March 1, 2018).

- 1 • The RICO Defendants
 - 2 ○ Purdue
 - 3 ○ Cephalon
 - 4 ○ Janssen
 - 5 ○ Endo
- 6 • The Front Groups
 - 7 ○ American Pain Foundation (“APF”)
 - 8 ○ American Academy of Pain Medicine (“AAPM”)
 - 9 ○ American Pain Society (“APS”)
 - 10 ○ Federation of State Medical Boards (“FSMB”)
 - 11 ○ U.S. Pain Foundation (“USPF”)
 - 12 ○ American Geriatrics Society (“AGS”)
- 13 • The KOLs
 - 14 ○ Dr. Russell Portenoy (“Dr. Portenoy”)
 - 15 ○ Dr. Lynn Webster (“Dr. Webster”)
 - 16 ○ Dr. Perry Fine (“Dr. Fine”)
 - 17 ○ Dr. Scott M. Fishman (“Dr. Fishman”))

18

19 448. The Opioid Marketing Enterprise is an ongoing and continuing

20 business organization that created and maintained systematic links, interpersonal

21 relationships and engaged in a pattern of predicate acts (i.e. racketeering activity)

22 in order to further the common purpose of the enterprise: unlawfully increasing

23 profits and revenues from the continued prescription and use of opioids for long-

24 term chronic pain. Each of the individuals and entities who formed the Opioid

25 Marketing Enterprise is an entity or person within the meaning of 18 U.S.C. §

26 1961(3) and acted to enable the common purpose and fraudulent scheme of the

27 Opioid Marketing Enterprise.

28

1 449. In order to accomplish the common purpose, members of the Opioid
2 Marketing Enterprise repeatedly and systematically misrepresented – affirmatively,
3 and through half-truths and omissions – that opioids are non-addictive and safe for
4 the effective treatment of long-term, chronic, non-acute and non-cancer pain, and
5 for other off-label uses not approved by the FDA. The Opioid Marketing Enterprise
6 misrepresented and concealed the serious risks and lack of corresponding benefits
7 of using opioids for long-term chronic pain. By making these misrepresentations,
8 the Opioid Marketing Enterprise ensured that a large number of opioid prescriptions
9 would be written and filled for chronic pain.

10 450. At all relevant times, the Opioid Marketing Enterprise: (a) had an
11 existence separate and distinct from each RICO Marketing Defendant and its
12 members; (b) was separate and distinct from the pattern of racketeering in which
13 the RICO Defendants engaged; (c) was an ongoing and continuing organization
14 consisting of individuals, persons, and legal entities, including each of the RICO
15 Marketing Defendants; (d) was characterized by interpersonal relationships
16 between and among each member of the Opioid Marketing Enterprise, including
17 between the RICO Marketing Defendants and each of the Front Groups and KOLs;
18 (e) had sufficient longevity for the enterprise to pursue its purpose; and (f)
19 functioned as a continuing unit.

20 451. The persons and entities engaged in the Opioid Marketing Enterprise
21 are systematically linked through contractual relationships, financial ties, personal
22 relationships, and continuing coordination of activities, as spearheaded by the RICO
23 Marketing Defendants.

24 452. Each of the RICO Marketing Defendants, and each member of the
25 Opioid Marketing Enterprise had systematic links to and personal relationships with
26 each other through joint participation in lobbying groups, trade industry
27 organizations, contractual relationships and continuing coordination of activities.
28 Each of the RICO Marketing Defendants coordinated their marketing efforts

1 through the same KOLs and Front Groups, based on their agreement and
 2 understanding that the Front Groups and KOLs were industry friendly and would
 3 work together with the RICO Marketing Defendants to advance the common
 4 purpose of the Opioid Marketing Enterprise.

5 **1. The RICO Defendants**

6 453. In addition to their systematic links to and personal relationships with
 7 the Front Groups and KOLS, described below, the RICO Marketing Defendants had
 8 systematic links to and personal relationships with each other through their
 9 participation in lobbying groups, trade industry organizations, contractual
 10 relationships and continuing coordination of activities, including but not limited to,
 11 the Pain Care Forum (“PCF”) and the Healthcare Distribution Alliance (“HDA”).

12 454. The PCF has been described as a coalition of drug makers, trade groups
 13 and dozens of non-profit organizations supported by industry funding. Plaintiffs
 14 are informed and believe that the PCF was created with the stated goal of offering
 15 a “setting where multiple organizations can share information” and “promote and
 16 support taking collaborative action regarding federal pain policy issues.” Plaintiffs
 17 are informed and believe that past APF President Will Rowe described the PCF as
 18 “a deliberate effort to positively merge the capacities of industry, professional
 19 associations, and patient organizations.”

20 455. The PCF recently became a national news story when it was
 21 discovered that lobbyists for members of the PCF, including the RICO Marketing
 22 Defendants, quietly shaped federal and state policies regarding the use of
 23 prescription opioids for more than a decade.

24 456. The Center for Public Integrity and The Associated Press obtained
 25 “internal documents shed[ding] new light on how drug makers and their allies
 26 shaped the national response to the ongoing wave of prescription opioid abuse.”²⁰³
 27

28 ²⁰³ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.),

Specifically, PCF members spent over \$740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.²⁰⁴

457. Not surprisingly, each of the RICO Marketing Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.²⁰⁵ In 2012, membership and participating organizations in the PCF included the HDA (of which all the RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), and Teva (the parent company of Cephalon).²⁰⁶ Each of the RICO Marketing Defendants worked together through the PCF to advance the interests of the Opioid Marketing Enterprise. But, the RICO Marketing Defendants were not alone, many of the RICO Marketing Defendants' Front Groups were also members of the PCF, including the American Academy of Pain Management, the American Pain Foundation, and the American Pain Society. Upon information and belief, the RICO Marketing Defendants' KOLs were also members of and participated in the PCF.

458. Through the Pain Care Forum, the RICO Marketing Defendants met regularly and in person to form and take action to further the common purpose of the Opioid Marketing Enterprise and shape the national response to the ongoing prescription opioid epidemic.

<https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

²⁰⁴ *Id.*

²⁰⁵ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf> (last visited March 8, 2018).

²⁰⁶ *Id.* Upon information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

1 459. Through the HDA – or Healthcare Distribution Alliance – the RICO
2 Marketing Defendants “strengthen[ed] . . . alliances”²⁰⁷ and took actions to further
3 the common purpose of the Opioid Marketing Enterprise.

4 460. Beyond strengthening alliances, the benefits of HDA membership
5 included the ability to, among other things, “network one on one with manufacturer
6 executives at HDA’s members-only Business and Leadership Conference,”
7 “participate on HDA committees, task forces and working groups with peers and
8 trading partners,” and “make connections.”²⁰⁸ Clearly, membership in the HDA
9 was an opportunity to create interpersonal and ongoing organizational relationships
10 and “alliances” between the RICO Marketing Defendants.

11 461. The closed meetings of the HDA’s councils, committees, task forces
12 and working groups provided the RICO Marketing Defendants with the opportunity
13 to work closely together, confidentially, to develop and further the common purpose
14 and interests of the Opioid Marketing Enterprise.

15 462. The HDA also offered multiple conferences, including annual business
16 and leadership conferences through which the RICO Marketing Defendants had an
17 opportunity to “bring together high-level executives, thought leaders and influential
18 managers . . . to hold strategic business discussions on the most pressing industry
19 issues.”²⁰⁹ The HDA and its conferences were significant opportunities for the
20 RICO Marketing Defendants to interact at the executive level and form and take
21 actions in furtherance of the common purpose of the Opioid Marketing Enterprise.
22

23 ²⁰⁷ Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed
24 on September 14, 2017),
25 [https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-](https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en)
26 [memberships-membership-benefits.ashx?la=en](https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en) (emphasis added).

27 ²⁰⁸ *Id.*

28 ²⁰⁹ Business and Leadership Conference – Information for Manufacturers,
Healthcare Distribution
Alliance [https://www.healthcaredistribution.org/events/2015-business-and-](https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers)
leadership-conference/blc-for-manufacturers (last accessed on September 14,
2017).

1 It is clear that the RICO Marketing Defendants embraced this opportunity by
2 attending and sponsoring these events.²¹⁰

3 463. The systematic contacts and personal relationships developed by the
4 RICO Marketing Defendants through the PCF and the HDA furthered the common
5 purpose of the Opioid Marketing Enterprise because it allowed the RICO Marketing
6 Defendants to coordinate the conduct of the Opioid Marketing Enterprise by,
7 including but not limited to, coordinating their interaction and development of
8 relationships with the Front Groups and KOLs.

9 **2. The Front Groups**

10 464. Each of the RICO Marketing Defendants had systematic links to and
11 personal relationships with Front Groups that operated as part of the Opioid
12 Marketing Enterprise to further the common purpose of unlawfully increasing sales
13 by misrepresenting the non-addictive and effective use of opioids for the treatment
14 of long-term chronic pain. As recently reported by the U.S. Senate in “*Fueling an*
15 *Epidemic*”:

16 The fact that these same manufacturers provided millions of dollars to
17 the groups described below suggests, at the very least, a direct link
18 between corporate donations and the advancement of opioids-friendly
19 messaging. By aligning medical culture with industry goals in this way,
many of the groups described in this report may have played a
significant role in creating the necessary conditions for the U.S. opioids
epidemic.²¹¹

20 465. “Patient advocacy organizations and professional societies like the
21 Front Groups ‘play a significant role in shaping health policy debates, setting
22 national guidelines for patient treatment, raising disease awareness, and educating
23 the public.’”²¹² “Even small organizations— with ‘their large numbers and
24 credibility with policymakers and the public’—have ‘extensive influence in specific
25

26 ²¹⁰ 2015 Distribution Management Conference and Expo, Healthcare Distribution
27 Alliance, [https://www.healthcaredistribution.org/events/2015-distribution-](https://www.healthcaredistribution.org/events/2015-distribution-management-conference)
management-conference (last accessed on September 14, 2017).

28 ²¹¹ Fueling an Epidemic, at p. 1.

²¹² *Id.* at p. 2

disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”²¹³ Indeed, as reflected below, the U.S. Senate’s report found that the RICO Marketing Defendants made nearly \$9 million worth of contributions to various Front Groups, including members of the Opioid Marketing Enterprise.²¹⁴

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue ²²	Janssen ²³	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	\$1,091,024.86	\$128,000.00	\$43,491.95	\$3,050.00 ²⁴	\$0.00	\$1,265,566.81
American Academy of Pain Medicine	\$725,584.95	\$83,975.00	\$332,100.00	\$57,750.00	\$0.00	\$1,199,409.95
AAPM Foundation	\$0.00	\$0.00	\$304,605.00	\$0.00	\$0.00	\$304,605.00
ACS Cancer Action Network	\$168,500.00 ²⁵	\$0.00	\$0.00	\$0.00	\$0.00	\$168,500.00
American Chronic Pain Association	\$312,470.00	\$50,000.00	\$54,670.00	\$0.00	\$0.00	\$417,140.00
American Geriatrics Society	\$11,785.00 ²⁶	\$0.00	\$0.00	\$0.00	\$0.00	\$11,785.00
American Pain Foundation	\$25,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$25,000.00
American Pain Society	\$542,259.52	\$88,500.00	\$288,750.00	\$22,965.00	\$20,250.00	\$962,724.52
American Society of Pain Educators	\$30,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$30,000.00
American Society of Pain Management Nursing	\$242,535.00	\$55,177.85 ²⁷	\$25,500.00 ²⁸	\$0.00	\$0.00	\$323,212.85
The Center for Practical Bioethics	\$145,095.00	\$18,000.00	\$0.00	\$0.00	\$0.00	\$163,095.00
The National Pain Foundation ²⁹	\$0.00	\$0.00	\$0.00	\$562,500.00	\$0.00	\$562,500.00
U.S. Pain Foundation	\$359,300.00	\$41,500.00	\$22,000.00	\$2,500,000.00 ³⁰	\$0.00	\$2,922,800.00
Washington Legal Foundation	\$500,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$500,000.00
	\$4,153,554.33	\$465,152.85	\$1,071,116.95	\$3,146,265.00	\$20,250.00	\$8,856,339.13

²¹³ *Id.*

²¹⁴ *Id.* at p. 3.

466. The Front Groups included in the Opioid Marketing Enterprise “have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies.”²¹⁵ And, as reflected below, many of the RICO Marketing Defendants’ Front Groups received the largest contributions:

FIGURE 5: Group Rankings by Manufacturer Payments, 2012-2017

U.S. Pain Foundation	\$2,922,800.00
Academy of Integrative Pain Management	\$1,265,566.81
American Academy of Pain Medicine	\$1,199,409.95
American Pain Society	\$962,724.52
The National Pain Foundation	\$562,500.00
Washington Legal Foundation	\$500,000.00
American Chronic Pain Association	\$417,140.00
American Society of Pain Management Nursing	\$323,212.85
AAPM Foundation	\$304,605.00
ACS Cancer Action Network	\$168,500.00
The Center for Practical Bioethics	\$163,095.00
American Society of Pain Educators	\$30,000.00
American Pain Foundation	\$25,000.00
American Geriatrics Society	\$11,785.00

467. But, the RICO Marketing Defendants connection with and control over the Front Groups did not end with financial contributions. Rather, the RICO Marketing Defendants made substantial contributions to physicians affiliated with the Front Groups totaling more than \$1.6 million.²¹⁶ Moreover, the RICO Marketing Defendants “made substantial payments to individual group executives,

²¹⁵ *Id.* at p. 3.

²¹⁶ *Id.* at p. 3.

staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.²¹⁷

468. As described in more detail below²¹⁸, the RICO Marketing Defendants “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”²¹⁹ They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding.”²²⁰

FIGURE 7: Purdue, Janssen, Insys, Depomed, and Mylan Payments to Groups and Group-Affiliated Individuals, 2012-Present⁴¹

	Payments to Group	Payments to Group-Affiliated Individuals	Total
U.S. Pain Foundation	\$2,922,800.00	\$126.20	\$2,922,926.20
The National Pain Foundation	\$562,500.00	\$839,848.84	\$1,402,348.84
Academy of Integrative Pain Management	\$1,265,566.81	\$30,223.42	\$1,295,790.23
American Academy of Pain Medicine	\$1,199,409.95	\$16,462.42	\$1,215,872.37
American Pain Society	\$962,724.52	\$95,474.56	\$1,058,199.08
AAPM Foundation	\$304,605.00	\$314,175.58	\$618,780.58
Washington Legal Foundation	\$500,000.00	N/A	\$500,000.00
American Chronic Pain Association	\$417,140.00	\$31,265.87	\$448,405.87
American Society of Pain Management Nursing	\$323,212.85	N/A	\$323,212.85
American Society of Pain Educators	\$30,000.00	\$280,765.92	\$310,765.92
The Center for Practical Bioethics	\$163,095.00	\$7,116.86	\$170,211.86
ACS Cancer Action Network	\$168,500.00	N/A	\$168,500.00
American Pain Foundation	\$25,000.00	N/A	\$25,000.00
American Geriatrics Society	\$11,785.00	\$194.13	\$11,979.13
Total	\$8,856,339.13	\$1,615,653.80	\$10,471,992.93

²¹⁷ *Id.* at p. 10.

²¹⁸ The activities that the Front Groups engaged in, and the misrepresentations that they made, in furtherance of the common purpose of the Opioid Marketing Enterprise are alleged more fully below, under the heading “Conduct of the Opioid Marketing Enterprise.”

²¹⁹ *Id.* at 12-15.

²²⁰ *Id.* at 12.

1 469. The systematic contacts and interpersonal relationships of the RICO
2 Marketing Defendants, and the Front Groups are further described below:

3 470. The American Pain Foundation (“APF”) – The American Pain
4 Foundation was the most prominent member of the RICO Defendants’ Front
5 Groups and was funded almost exclusively by the RICO Marketing Defendants.
6 Plaintiffs are informed and believe that APF received more than \$10 million in
7 funding from the RICO Marketing Defendants between 2007 and the close of its
8 business in May 2012. The APF had multiple contacts and personal relationships
9 with the RICO Marketing Defendants through its many publishing and educational
10 programs, funded and supported by the RICO Marketing Defendants. Plaintiffs are
11 further informed and believe that between 2009 and 2010, APF received more than
12 eighty percent (80%) of its operating budget from pharmaceutical industry sources.
13 Including industry grants for specific projects, APF received about \$2.3 million
14 from industry sources out of total income of about \$2.85 million in 2009; its budget
15 for 2010 projected receipts of roughly \$2.9 million from drug companies, out of
16 total income of about \$3.5 million. By 2011, upon information and belief, APF was
17 entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo,
18 and others.

19 471. On information and belief, APF was often called upon to provide
20 “patient representatives” for the RICO Marketing Defendants’ promotional
21 activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s Talk
22 Pain.” APF functioned largely as an advocate for the interests of the RICO
23 Marketing Defendants, not patients. Indeed, upon information and belief, as early
24 as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to
25 “strategically align its investments in nonprofit organizations that share [its]
26 business interests.”

27 472. APF is also credited with creating the PCF in 2004. Plaintiffs are
28 informed and believe that the PCF was created with the stated goal of offering a

1 “setting where multiple organizations can share information” and “promote and
 2 support taking collaborative action regarding federal pain policy issues.” Plaintiffs
 3 are informed and believe that past APF President Will Rowe described the PCF as
 4 “a deliberate effort to positively merge the capacities of industry, professional
 5 associations, and patient organizations.”

6 473. Upon information and belief, representatives of the RICO Marketing
 7 Defendants, often at informal meetings at conferences, suggested activities and
 8 publications for APF to pursue. APF then submitted grant proposals seeking to
 9 fund these activities and publications, knowing that drug companies would support
 10 projects conceived as a result of these communications.

11 474. Furthermore, APF’s Board of Directors was largely comprised of
 12 doctors who were on Defendants’ payrolls, either as consultants or speakers at
 13 medical events.²²¹ As described below, many of the KOLs involved in the Opioid
 14 Marketing Enterprise also served in leadership positions within the APF.

15 475. In December 2011, a ProPublica investigation found that in 2010,
 16 nearly 90% of APF’s funding came from the drug and medical device community,
 17 including RICO Marketing Defendants.²²² More specifically, APF received
 18 approximately \$2.3 million from industry sources out of total income of \$2.85
 19 million in 2009. It’s budget for 2010 projected receipt of approximately \$2.9
 20 million from drug companies, out of total income of approximately \$3.5 million.
 21 In May 2012, the U.S. Senate Finance Committee began looking into APF to
 22 determine the links, financial and otherwise, between the organization and the
 23 manufacturers of opioid painkillers. Within days of being targeted by the Senate
 24

25 ²²¹ Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica
 26 (Dec. 23, 2011), <https://www.propublica.org/article/the-champion-of-painkillers>.

27 ²²² Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of*
 28 *painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011),
https://www.washingtonpost.com/national/healthscience/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probefinds/2011/12/20/gIQAgvczDP_story.html?utm_term=.22049984c606.

1 investigation, APF's Board voted to dissolve the organization "due to irreparable
2 economic circumstances." APF "cease[d] to exist, effective immediately."²²³

3 476. The American Academy of Pain Medicine ("AAPM") – The AAPM
4 was another Front Group that had systematic ties and personal relationships with
5 the RICO Defendants. AAPM received over \$2.2 million in funding since 2009
6 from opioid manufacturers. AAPM maintained a corporate relations council, whose
7 members paid \$25,000 per year (on top of other funding) to participate. The
8 benefits included allowing members to present educational programs at off-site
9 dinner symposia in connection with AAPM's marquee event – its annual meeting
10 held in Palm Springs, California, or other resort locations. AAPM describes the
11 annual event as an "exclusive venue" for offering education programs to doctors.
12 Membership in the corporate relations council also allowed drug company
13 executives and marketing staff to meet with AAPM executive committee members
14 in small settings. The RICO Marketing Defendants were all members of the council
15 and presented deceptive programs to doctors who attended this annual event.²²⁴

16 477. The RICO Marketing Defendants internally viewed AAPM as
17 "industry friendly," with RICO Defendants' advisors and speakers among its active
18 members. The RICO Marketing Defendants attended AAPM conferences, funded
19 its CMEs and satellite symposia, and distributed its publications. AAPM
20 conferences heavily emphasized sessions on opioids. AAPM presidents have
21 included top industry-supported KOLs like Perry Fine and Lynn Webster.

22
23
24
25 ²²³ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012,
26 https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

27 ²²⁴ The American Academy of Pain Medicine, *Pain Medicine DC The Governing*
28 *Voices of Pain: Medicine, Science, and Government*, March 24-27, 2011,
<http://www.painmed.org/files/2011-annual-meeting-program-book.pdf>.

1 478. Upon information and belief, representatives of the RICO Marketing
 2 Defendants, often at informal meetings at conferences, suggested activities and
 3 publications for AAPM to pursue. AAPM then submitted grant proposals seeking
 4 to fund these activities and publications, knowing that drug companies would
 5 support projects conceived as a result of these communications.

6 479. Plaintiffs are informed and believe that members of AAPM's Board of
 7 Directors were doctors who were on the RICO Marketing Defendants' payrolls,
 8 either as consultants or speakers at medical events. As described below, many of
 9 the KOLs involved in the Opioid Marketing Enterprise also served in leadership
 10 positions within the AAPM.

11 480. The American Pain Society ("APS") – The APS was another Front
 12 Group with systematic connections and interpersonal relationships with the RICO
 13 Marketing Defendants. APS was one of the Front Groups investigated by Senators
 14 Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their
 15 investigation of "extensive ties between companies that manufacture and market
 16 opioids and non-profit organizations" that "helped created a body of dubious
 17 information favoring opioids."²²⁵

18 481. Upon information and belief, representatives of the RICO Marketing
 19 Defendants, often at informal meetings at conferences, suggested activities and
 20 publications for APS to pursue. APS then submitted grant proposals seeking to
 21 fund these activities and publications, knowing that drug companies would support
 22 projects conceived as a result of these communications.

23 482. Plaintiffs are informed and believe that members of APS's Board of
 24 Directors were doctors who were on the RICO Marketing Defendants' payrolls,

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 26
 27 ²²⁵ Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine
 28 Underwood, Executive Director (May 8, 2012), American Pain Society,
<https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf>.

1 either as consultants or speakers at medical events. As described below, many of
 2 the KOLs involved in the Opioid Marketing Enterprise also served in leadership
 3 positions within the APS.

4 483. The Federation of State Medical Boards (“FSMB”) – FSMB was
 5 another Front Group with systematic connections and interpersonal relationships
 6 with the RICO Marketing Defendants. In addition to the contributions reported in
 7 *Fueling an Epidemic*, a June 8, 2012 letter submitted by FSMB to the Senate
 8 Finance Committee disclosed substantial payments from the RICO Marketing
 9 Defendants beginning in 1997 and continuing through 2012.²²⁶ Not surprisingly,
 10 the FSMB was another one of the Front Groups investigated by Senators Grassley
 11 and Baucus, as evidenced by their May 8, 2012 letter arising out of their
 12 investigation of “extensive ties between companies that manufacture and market
 13 opioids and non-profit organizations” that “helped created a body of dubious
 14 information favoring opioids.”²²⁷

15 484. The U.S. Pain Foundation (“USPF”) – The USPF was another Front
 16 Group with systematic connections and interpersonal relationships with the RICO
 17 Marketing Defendants. The USPF was one of the largest recipients of contributions
 18 from the RICO Marketing Defendants, collection nearly \$3 million in payments
 19 between 2012 and 2015 alone.²²⁸ The USPF was also a critical component of the
 20 Opioid Marketing Enterprise’s lobbying efforts to reduce the limits on over-
 21 prescription. The U.S. Pain Foundation advertises its ties to the RICO Marketing
 22 Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo,
 23

24 ²²⁶ June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators
 25 Max Baucus and Charles Grassley.

26 ²²⁷ Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine
 27 Underwood, Executive Director (May 8, 2012), American Pain Society,
 28 <https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf>.

²²⁸ *Fueling an Epidemic*, at p. 4.

Purdue, McNeil (i.e. Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members.²²⁹ Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

485. American Geriatrics Society (“AGS”) – The AGS was another Front Group with systematic connections and interpersonal relationships with the RICO Defendants. The AGS was a large recipient of contributions from the RICO Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with the RICO Marketing Defendants to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons, hereinafter “2002 AGS Guidelines”) and 2009 (Pharmacological Management of Persistent Pain in Older Persons,²³⁰ hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009.²³¹ AGS’s complicity in the common purpose of the Opioid Marketing Enterprise is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

486. Upon information and belief, representatives of the RICO Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant

²²⁹ *Id.* at 12; Transparency, U.S. Pain Foundation, <https://uspainfoundation.org/transparency/> (last accessed on March 9, 2018).

²³⁰ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).

²³¹ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

1 proposals seeking to fund these activities and publications, knowing that drug
2 companies would support projects conceived as a result of these communications.

3 487. Plaintiffs are informed and believe that members of AGS Board of
4 Directors were doctors who were on the RICO Marketing Defendants' payrolls,
5 either as consultants or speakers at medical events. As described below, many of
6 the KOLs involved in the Opioid Marketing Enterprise also served in leadership
7 positions within the AGS.

8 488. There was regular communication between each of the RICO
9 Marketing Defendants, Front Groups and KOLs, in which information was shared,
10 misrepresentations were coordinated, and payments were exchanged. Typically,
11 the coordination, communication and payment occurred, and continues to occur,
12 through the use of the wires and mail in which the RICO Markets Defendants, Front
13 Groups, and KOLs share information necessary to overcome objections and
14 resistance to the use of opioids for chronic pain. The RICO Marketing Defendants,
15 Front Groups and KOLs functioned as a continuing unit for the purpose of
16 implementing the Opioid Marketing Enterprise's scheme and common purpose, and
17 each agreed to take actions to hide the scheme and continue its existence.

18 489. At all relevant times, the Front Groups were aware of the RICO
19 Marketing Defendants' conduct, were knowing and willing participants in that
20 conduct, and reaped benefits from that conduct. Each Front Group also knew, but
21 did not disclose, that the other Front Groups were engaged in the same scheme, to
22 the detriment of consumers, prescribers, and The County. But for the Opioid
23 Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive
24 to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing
25 Enterprise to their members and constituents. By failing to disclose this
26 information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme
27 and common purpose, and reaped substantial benefits.

3. The KOLs

490. Similarly, each of the RICO Marketing Defendants financed, supported, utilized and relied on the same KOLs by paying, financing, supporting, managing, directing, or overseeing, and/or relying on their work. On Information and belief, the RICO Marketing Defendants cultivated this small circle of doctors solely because they favored the aggressive treatment of chronic pain with opioids.

491. The RICO Marketing Defendants and the Opioid Marketing Enterprise relied on their KOLs to serve as part of their speakers bureaus and to attend programs with speakers bureaus. The RICO Marketing Defendants graded their KOLs on performance, post-program sales, and product usage. Furthermore, the RICO Marketing Defendants expected their KOLs to stay “on message,” and obtained agreements from them, in writing, that “all slides must be presented in their entirety and without alterations . . . and in sequence.”

492. The RICO Marketing Defendants’ KOLs have been at the center of the Opioid Marketing Enterprise’s marketing efforts, presenting the false appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. As described in more detail below, the KOLs have written, consulted, edited, and lent their names to books and articles, and given speeches, and CMEs supporting chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of the pro-opioid Front Groups identified above.

493. The RICO Marketing Defendants and KOLS all had systematic connections and interpersonal relationships, as described below, through the KOLs receipt of payments from the RICO Marketing Defendants and Front Groups, the KOLs’ authoring, publishing, speaking, and educating on behalf of the RICO Marketing Defendants, and their leadership roles and participation in the activities

1 of the Front Groups, which were in turn financed by the RICO Marketing
2 Defendants.

3 494. The systematic contacts and interpersonal relationships of the KOLs
4 with the RICO Marketing Defendants and Front Groups are described below:

5 495. Dr. Russell Portenoy – Dr. Portenoy was one of the main KOLs that
6 the RICO Marketing Defendants identified and promoted to further the common
7 purpose of the Opioid Marketing Enterprise. Dr. Portenoy received research
8 support, consulting fees, and honoraria from the RICO Defendants, and was a paid
9 consultant to various RICO Marketing Defendants. Dr. Portenoy was instrumental
10 in opening the door for the regular use of opioids to treat chronic pain. Dr. Portenoy
11 is credited as one of the authors on a primary pillar of the RICO Marketing
12 Defendants’ misrepresentation regarding the risks and benefits of opioid use.²³² Dr.
13 Portenoy had financial relationships with at least a dozen pharmaceutical
14 companies, most of which produced prescription opioids.²³³

15 496. In exchange for the payments he received from the RICO Marketing
16 Defendants, Dr. Portenoy is credited as one of the authors on a primary pillar of the
17

18
19 ²³² In 1986, the medical journal *Pain*, which would eventually become the official
20 journal of the American Pain Society (“APS”), published an article by Portenoy
21 and Foley summarizing the results of a “study” of 38 chronic non-cancer pain
22 patients who had been treated with opioid painkillers. Portenoy and Foley
23 concluded that, for non-cancer pain, opioids “can be safely and effectively
24 prescribed to selected patients with relatively little risk of producing the
25 maladaptive behaviors which define opioid abuse.” However, their study was
26 neither scientific nor did it meet the rigorous standards commonly used to evaluate
27 the validity and strength of such studies in the medical community. For instance,
28 there was no placebo control group, and the results were retroactive (asking
patients to describe prior experiences with opioid treatment rather than less biased,
in-the-moment reports). The authors themselves advised caution, stating that the
drugs should be used as an “alternative therapy” and recognizing that longer term
studies of patients on opioids would have to be performed. None were. See Russell
K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-
malignant pain: report of 38 cases*, 25(2) *Pain* 171-86 (May 1986).

²³³ Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got
Hooked, and Why It’s So Hard to Stop*, (Johns Hopkins University Press 2016), at
59 (citing Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and
Death* (St. Martin’s Press, 1st Ed 2003)).

1 RICO Marketing Defendants' misrepresentation regarding the risks and benefits of
 2 opioids.²³⁴ Dr. Portenoy, published, spoke, consulted, appeared in advertisements
 3 and on television broadcasts, and traveled the country to travel the country to
 4 promote more liberal prescribing for many types of pain and conduct continuing
 5 medical education ("CME") seminars sponsored by the RICO Marketing
 6 Defendants and Front Groups.

7 497. Dr. Portenoy was also a critical component of the RICO Marketing
 8 Defendants' control over their Front Groups, and the Front Groups support of the
 9 Opioid Marketing Enterprise's common purpose. Specifically, Dr. Portenoy sat as
 10 a Director on the board of the APF. He was also the President of the APS.

11 498. In a 2011 interview released by Physicians for Responsible Opioid
 12 Prescribing, Dr. Portenoy admitted that his earlier work relied on evidence that was
 13 not "real" and left real evidence behind, all in furtherance of the Opioid Marketing
 14 Enterprise's common purpose:

15 I gave so many lectures to primary care audiences in which the Porter
 16 and Jick article was just one piece of data that I would then cite, and I
 17 would cite six, seven, maybe ten different avenues of thought or
 18 avenues of evidence, none of which represented real evidence, and yet
 19 what I was trying to do was to create a narrative so that the primary care
 20 audience would look at this information in [total] and feel more
 comfortable about opioids in a way they hadn't before. In essence this

21 ²³⁴ In 1986, the medical journal Pain, which would eventually become the official
 22 journal of the American Pain Society ("APS"), published an article by Portenoy
 23 and Foley summarizing the results of a "study" of 38 chronic non-cancer pain
 24 patients who had been treated with opioid painkillers. Portenoy and Foley
 25 concluded that, for non-cancer pain, opioids "can be safely and effectively
 26 prescribed to selected patients with relatively little risk of producing the
 27 maladaptive behaviors which define opioid abuse." However, their study was
 28 neither scientific nor did it meet the rigorous standards commonly used to evaluate
 the validity and strength of such studies in the medical community. For instance,
 there was no placebo control group, and the results were retroactive (asking
 patients to describe prior experiences with opioid treatment rather than less biased,
 in-the-moment reports). The authors themselves advised caution, stating that the
 drugs should be used as an "alternative therapy" and recognizing that longer term
 studies of patients on opioids would have to be performed. None were. See Russell
 K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-
 malignant pain: report of 38 cases*, 25(2) Pain 171-86 (May 1986).

1 was education to destigmatize [opioids], and because the primary goal
 2 was to destigmatize, we often left evidence behind.²³⁵

3 499. Dr. Lynn Webster – Dr. Webster was a critical component of the
 4 Opioid Marketing Enterprise, including advocating the RICO Marketing
 5 Defendants’ fraudulent messages regarding prescription opioids and had systematic
 6 contacts and personal relationships with the RICO Marketing Defendants and the
 7 Front Groups.

8 500. Dr. Webster was the co-founder and Chief Medical Director of an
 9 otherwise unknown pain clinic in Salt Lake City, Utah (Lifetree Clinical Research),
 10 who went on to become one of the RICO Marketing Defendants’ main KOLs. Dr.
 11 Webster was the President of American Academy of Pain Medicine (“AAPM”) in
 12 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo
 13 special advertising supplements touting Opana ER. Dr. Webster was the author of
 14 numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr.
 15 Webster was receiving significant funding from the RICO Marketing Defendants
 16 (including nearly \$2 million from Cephalon alone).

17 501. During a portion of his time as a KOL, Dr. Webster was under
 18 investigation for overprescribing by the U.S. Department of Justice’s Drug
 19 Enforcement Agency, which raided his clinic in 2010. Although the investigation
 20 was closed without charges in 2014, more than twenty (20) of Dr. Webster’s former
 21 patients at the Lifetree Clinic have died of opioid overdoses.

22 502. Dr. Webster created and promoted the Opioid Risk Tool, a five
 23 question, one-minute screening tool relying on patient self-reports that purportedly
 24 allows doctors to manage the risk that their patients will become addicted to or
 25 abuse opioids. The claimed ability to pre-sort patients likely to become addicted is
 26 an important tool in giving doctors confidence to prescribe opioids long-term, and,

27 ²³⁵ Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube
 28 (Oct. 30, 2011),
<https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

1 for this reason, references to screening appear in various industry-supported
 2 guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
 3 websites run by Endo, Janssen, and Purdue.

4 503. Dr. Webster is also credited as one of the leading proponents of
 5 "pseudoaddiction" that the RICO Marketing Defendants, Front Groups and KOLs
 6 disseminated as part of the common purpose of the Opioid Marketing Enterprise.

7 504. Plaintiff The County is informed and believes that in exchange for the
 8 payments he received from the RICO Marketing Defendants, Dr. Webster
 9 published, spoke, consulted, appeared in advertisements and on television
 10 broadcasts, and traveled the country to promote more liberal prescribing of opioids
 11 for many types of pain and conduct CME seminars sponsored by the RICO
 12 Marketing Defendants and Front Groups.

13 505. Like Dr. Portenoy, Dr. Webster later reversed his opinion and
 14 disavowed his previous work on and opinions regarding pseudoaddiction.
 15 Specifically, Dr. Webster acknowledged that "[pseudoaddiction] obviously became
 16 too much of an excuse to give patients more medication."²³⁶

17 506. Dr. Perry Fine – Dr. Webster was a critical component of the Opioid
 18 Marketing Enterprise, including advocating the RICO Marketing Defendants'
 19 fraudulent messages regarding prescription opioids and had systematic contacts and
 20 personal relationships with the RICO Marketing Defendants and the Front Groups.

21 507. Dr. Fine was originally a doctor practicing in Utah, who received
 22 support from the RICO Marketing Defendants, including Janssen, Cephalon, Endo,
 23 and Purdue. Dr. Fine's ties to the RICO Marketing Defendants have been well
 24 documented.²³⁷ He has authored articles and testified in court cases and before state
 25

26 ²³⁶ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J.
 27 Sentinel, Feb. 18, 2012,
 28 <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

²³⁷ Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM),

1 and federal committees, and he served as president of the AAPM, and argued
 2 against legislation restricting high-dose opioid prescription for non-cancer patients.
 3 Multiple videos featured Fine delivering educational talks about prescription
 4 opioids. He even testified in a trial that the 1,500 pills a month prescribed to
 5 celebrity Anna Nicole Smith for pain did not make her an addict before her death.²³⁸
 6 He has also acknowledged having failed to disclose numerous conflicts of interest.

7 508. Dr. Fine was also a critical component of the RICO Marketing
 8 Defendants' control over their Front Groups, and the Front Groups support of the
 9 Opioid Marketing Enterprise's common purpose. Specifically, Dr. Fine served on
 10 the Board of Directors of APF and served as the President of the AAPM in 2011.

11 509. Plaintiff The County is informed and believes that in exchange for the
 12 payments he received from the RICO Marketing Defendants, Dr. Fine published,
 13 spoke, consulted, appeared in advertisements and on television broadcasts, and
 14 traveled the country to promote more liberal prescribing of opioids for many types
 15 of pain and conduct CME seminars sponsored by the RICO Marketing Defendants
 16 and Front Groups.

17 510. Dr. Scott M. Fishman – Dr. Fishman was a critical component of the
 18 Opioid Marketing Enterprise, including advocating the RICO Marketing
 19 Defendants' fraudulent messages regarding prescription opioids and had systematic
 20 contacts and personal relationships with the RICO Marketing Defendants and the
 21 Front Groups.

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 26 <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>

27 ²³⁸ Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle
 28 Times (Sept. 22, 2010, 5:16 PM),
<http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smithwas-addicted/>.

1 511. Although Dr. Fishman did not receive direct financial payments from
2 the RICO Marketing Defendants, his ties to the opioid drug industry are legion.²³⁹

3 512. As Dr. Fishman's personal biography indicates, he is critical
4 component of the RICO Marketing Defendants' control over their Front Groups,
5 and the Front Groups support of the Opioid Marketing Enterprise's common
6 purpose. Specifically, Dr. Fishman is an "internationally recognized expert on pain
7 and pain management" who has served in "numerous leadership roles with the goal
8 to alleviate pain."²⁴⁰ Dr. Fishman's roles in the pain industry include "past president
9 of the American Academy of Pain Medicine [AAPM], past chairman of the board
10 of directors of the American Pain Foundation [APF], and past board member of the
11 American Pain Society [APS]."²⁴¹ Dr. Fishman is also "the immediate past chair
12 and current member of the Pain Care Coalition of the American Society of
13 Anesthesiologists, American Pain Society, and Academy of Pain Medicine."²⁴² Dr.
14 Fishman's leadership positions within the central core of the RICO Marketing
15 Defendants' Front Groups was a direct result of his participation in the Opioid
16 Marketing Enterprise and agreement to cooperate with the RICO Marketing
17 Defendants' pattern of racketeering activity.

18 513. Plaintiff The County is informed and believes that in exchange for the
19 payments he received from the RICO Marketing Defendants, Dr. Fishman
20 published, spoke, consulted, appeared in advertisements and on television
21 broadcasts, and traveled the country to promote more liberal prescribing of opioids
22
23

24 _____
25 ²³⁹ Scott M. Fishman, M.D., Professor, U.C. Davis Health, Center for Advancing
26 Pain Relief,
27 [https://www.ucdmc.ucdavis.edu/advancingpainrelief/our_team/Scott_Fishman.htm](https://www.ucdmc.ucdavis.edu/advancingpainrelief/our_team/Scott_Fishman.html)
28 l (accessed on February 28, 2018).

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² *Id.*

1 for many types of pain and conduct CME seminars sponsored by the RICO
2 Marketing Defendants and Front Groups.

3 514. There was regular communication between each of the RICO
4 Marketing Defendants, Front Groups and KOLs, in which information was shared,
5 misrepresentations are coordinated, and payments were exchanged. Typically, the
6 coordination, communication and payment occurred, and continues to occur,
7 through the use of the wires and mail in which the RICO Marketing Defendants,
8 Front Groups, and KOLs share information regarding overcoming objections and
9 resistance to the use of opioids for chronic pain. The RICO Marketing Defendants,
10 Front Groups and KOLs functioned as a continuing unit for the purpose of
11 implementing the Opioid Marketing Enterprise's scheme and common purpose, and
12 each agreed to take actions to hide the scheme and continue its existence.

13 515. At all relevant times, the KOLs were aware of the RICO Marketing
14 Defendants' conduct, were knowing and willing participants in that conduct, and
15 reaped benefits from that conduct. The RICO Marketing Defendants selected KOLs
16 solely because they favored the aggressive treatment of chronic pain with opioids.
17 The RICO Marketing Defendants' support helped the KOLs become respected
18 industry experts. And, as they rose to prominence, the KOLs falsely touted the
19 benefits of using opioids to treat chronic pain, repaying the RICO Marketing
20 Defendants by advancing their marketing goals. The KOLs also knew, but did not
21 disclose, that the other KOLs and Front Groups were engaged in the same scheme,
22 to the detriment of consumers, prescribers, and The County. But for the Opioid
23 Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to
24 disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing
25 Enterprise, and to protect their patients and the patients of other physicians. By
26 failing to disclose this information, KOLs furthered the Opioid Marketing
27 Enterprise's scheme and common purpose, and reaped substantial benefits.

1 516. As public scrutiny and media coverage focused on how opioids
 2 ravaged communities in California and throughout the United States, the Front
 3 Groups and KOLS did not challenge the RICO Marketing Defendants'
 4 misrepresentations, seek to correct their previous misrepresentations, terminate
 5 their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of
 6 using opioids for chronic pain outweighed their benefits and were not supported by
 7 medically acceptable evidence.

8 517. The RICO Marketing Defendants, Front Groups and KOLs engaged in
 9 certain discrete categories of activities in furtherance of the common purpose of the
 10 Opioid Marketing Enterprise. As reported in *Fueling an Epidemic*, the Opioid
 11 Marketing Enterprise's conduct in furtherance of the common purpose of the
 12 Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of
 13 addiction and safe use of prescription opioids for long-term chronic pain; (2)
 14 lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or
 15 undermine CDC guidelines; and (4) efforts to limit prescriber accountability. The
 16 misrepresentations made in these publications are described in the following
 17 section.

18 518. Efforts to Minimize the Risk of Addiction and Promote Opioid Use As
 19 Safe for Long-Term Treatment of Chronic Pain – Members of the Opioid Marketing
 20 Enterprise furthered the common purpose of the enterprise by publishing and
 21 disseminating statements that minimized the risk of addiction and misrepresented
 22 the safety of using prescription opioids for long-term treatment of chronic, non-
 23 acute, and non-cancer pain. The categories of misrepresentations made by the
 24 Opioid Marketing Enterprise and the RICO Defendants included the following:²⁴³

25
 26
 27 ²⁴³ As noted below, the earliest misrepresentations disseminated by the RICO
 28 Defendants and the Opioid Marketing Enterprise began in 1997 and has continued
 unabated since that time. Therefore, this list is alleged as fully and completely as
 possible.

- 1 • The Use of Opioids for the Treatment of Chronic Pain: A Consensus
2 Statement From the American Academy of Pain Medicine and the American
3 Pain Society, 13 Clinical J. Pain 6 (1997). The “landmark consensus” was
4 published by the AAPM and APS. Dr. Portenoy was the sole consultant. A
5 member of Purdue’s speaker bureau authored the consensus.
- 6 • *Model Guidelines for the Use of Controlled Substances for the Treatment of*
7 *Pain* (1998, 2004, 2007).²⁴⁴ These guidelines, originally published by the
8 FSMB in collaboration with RICO Defendants, advocated that opioids were
9 “essential” and that “misunderstanding of addiction” contributed to
10 undertreated pain.
- 11 • *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on*
12 *Health, Education, Labor and Pensions, Testimony by John D. Giglio, M.A.,*
13 *J.D., Executive Direction of the APF (2002.)*²⁴⁵
- 14 • *The Management of Persistent Pain in Older Persons* (2002). These
15 guidelines were published by AGS with substantial funding from Endo,
16 Purdue and Janssen.
- 17 • *Overview of Management Options* (2003, 2007, 2010, and 2013).²⁴⁶ This
18 CME was edited by Dr. Portenoy, sponsored by Purdue, and published by the
19 American Medical Association. It taught that opioids, unlike non-
20 prescription pain medication are safe at high doses.

23 ²⁴⁴ *Model Policy for the Use of Controlled Substances for the Treatment of Pain*,
24 Federation of State Medical Boards of the United States, May 2004,
25 https://www.ihs.gov/painmanagement/includes/themes/newihstheme/display_objects/documents/modelpolicytreatmentpain.pdf (last accessed on March 9, 2018).

26 ²⁴⁵ *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health,*
27 *Education, Labor and Pensions, Testimony by John D. Giglio, M.A., J.D.,*
28 *Executive Direction of the APF (2002.)*

²⁴⁶ Portenoy, et al., *Overview of Management Options*, <https://cme.ama-assn.org/activity/1296783/detail.aspx>. On information and belief, this CME was published by the American Medical Association in 2003, 2007, 2010, and 2013.

- 1 • *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004).²⁴⁷ This
2 article, published by Endo Pharmaceuticals advocated that withdrawal and
3 needing to take higher dosages are not signs of addiction.
- 4 • Interview by Paula Moyer with Scott M. Fishman, M.D. (2005). Dr. Fishman
5 advocated that “the risks of addiction are . . . small and can be managed.”²⁴⁸
- 6 • Open-label study of fentanyl effervescent buccal tablets in patients with
7 chronic pain and breakthrough pain: interim safety and tolerability results
8 (2006).²⁴⁹ Dr. Webster gave this CME, sponsored by Cephalon, that
9 misrepresented that opioids were safe for the treatment of non-cancer pain.
- 10 • *Treatment Options: A Guide for People Living With Pain* (2007). This
11 document was published by the APF and sponsored by Cephalon and
12 Purdue.²⁵⁰
- 13 • *Responsible Opioid Prescribing: A Physician’s Guide* (2007).²⁵¹ This book,
14 authored by Dr. Fishman was financed by the FSMB with funding from
15 Cephalon, Endo and Purdue.

16
17
18 ²⁴⁷ Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral*
19 *Opioid Analgesics*, Endo Pharmaceuticals (2004),
20 <https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics> (last accessed March 8, 2018).

21 ²⁴⁸ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of
22 Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ.
of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

23 ²⁴⁹ Hale ME, Webster LR, Peppin JF, Messina J. Open-label study of fentanyl
24 effervescent buccal tablets in patients with chronic pain and breakthrough pain:
25 interim safety and tolerability results. Program and abstracts of the annual meeting
of the American Academy of Pain Medicine; February 22-25, 2006; San Diego,
California. Abstract 120. Published with permission of Lynn R. Webster, MD,
https://www.medscape.org/viewarticle/524538_2 (accessed on March 6, 2018).

26 ²⁵⁰ Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007)
[hereinafter APF, *Treatment Options*],
27 <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
accessed on March 8, 2018).

28 ²⁵¹ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9
(Waterford Life Sciences 2007).

- 1 • *Avoiding Opioid Abuse While Managing Pain* (2007).²⁵² This book, co-
2 authored by Dr. Webster, misrepresented that for prescribers facing signs of
3 aberrant behavior, increasing the dose in “most cases . . . should be a
4 clinician’s first response.”
- 5 • *Screeners and Opioid Assessment for Patients with Pain (SOAPP)® Version*
6 *1.0-SF* (2008).²⁵³ This screening tool was published by the National
7 Institutes of Health with support from Endo through an educational grant,
8 and advocated that most patients are able to successfully remain on long-term
9 opioid therapy without significant problems.
- 10 • *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*
11 (2007).²⁵⁴ This article, sponsored by Endo, misrepresented that opioids are a
12 highly effective class of analgesic drugs.
- 13 • *Opioid-Based Management of Persistent and Breakthrough Pain* (2008).²⁵⁵
14 This document was written by Dr. Fine and sponsored by an educational grant
15 from Cephalon. Dr. Fine advocated for the prescription of rapid onset opioids
16 “in patients with non-cancer pain.”
- 17 • *Optimizing Opioid Treatment for Breakthrough Pain* (2008).²⁵⁶ Dr. Webster
18 presented an online seminar (webinar) sponsored by Cephalon, that
19

20 ²⁵² Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain*
21 (2007).

22 ²⁵³ *Screeners and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-*
23 *SF*, PainEdu.org, 2008, [https://www.nhms.org/sites/default/files/Pdfs/SOAPP-](https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf)
24 [5.pdf](https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf) (last accessed on March 8, 2018).

25 ²⁵⁴ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for*
26 *Chronic Pain*, Pain Med. News,
27 https://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last visited
28 on March 8, 2018).

²⁵⁵ Perry G Fine, MD, et al. *Opioid-Based Management of Persistent and*
26 *Breakthrough Pain*, Pain Medicine News,
27 [https://www.yumpu.com/en/document/view/11409251/opioid-based-management-](https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain)
28 [of-persistent-and-breakthrough-pain](https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain) (accessed on February 27, 2018).

²⁵⁶ Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape,
http://www.medscape.org/viewarticle/563417_6 (last visited Dec. 11, 2017).

misrepresented that non-opioid analgesics and combination opioids containing non-opioids are less effective because of dose limitations.

- *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain* (2009).²⁵⁷ These guidelines were published by AAPM and APS. Fourteen of the twenty-one panel members, including Dr. Portenoy and Dr. Fine, received support from the RICO Defendants.
- *Pharmacological Management of Persistent Pain in Older Persons* (2009).²⁵⁸ These guidelines were published by AGS, with substantial funding from Endo, Purdue, and Janssen, updated the 2002 guidelines and misrepresented that the risks of addiction are exceedingly low.
- *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*,²⁵⁹ American Pain Foundation, 2009. This article was published in 2009 and sponsored by Purdue.
- *Finding Relief: Pain Management for Older Adults*, (2009).²⁶⁰ This article was a collaboration between the American Geriatrics Society, AAPM and Janssen.

²⁵⁷ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

²⁵⁸ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).

²⁵⁹ *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq + Afghanistan Veterans, <http://web.archive.org/web/20100308224011/http://coalitionforveterans.org:80/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families> (last visited March 1, 2018).

²⁶⁰ *Finding Relief, Pain Management for Older Adults*, (2009).

- 1 • Good Morning America (2010). Dr. Portenoy appeared on Good Morning
2 America and stated that “Addiction, when treating pain, is distinctly
3 uncommon.”²⁶¹
- 4 • *A Policymaker’s Guide to Understanding Pain & Its Management*, American
5 Pain Foundation (2011).²⁶² APF published this document, that was
6 sponsored by Purdue, which argued that the notion of strong pain leading to
7 addiction is a common misconception.
- 8 • *Managing Patient’s Opioid Use: Balancing the Need and the Risk* (2011).²⁶³
9 Dr. Webster presented a webinar, sponsored by Purdue, that misrepresented
10 the ability to use risk screen tools, urine samples and patient agreements to
11 prevent overuse and overdose death.
- 12 • *Safe and Effective Opioid Rotation* (2012).²⁶⁴ This CME, delivered by Dr.
13 Fine, that is also available online, advocated for the safe and non-addictive
14 use of opioids to treat cancer and non-cancer patients over a person’s
15 “lifetime.”
- 16 • *Pain: Opioid Facts* (2012).²⁶⁵ This document was published online on
17 Endo’s website painknowledge.org and advocated for the use of opioids and
18

19
20 ²⁶¹ Good Morning America (ABC television broadcast Aug. 30, 2010).

21 ²⁶² *A Policymaker’s Guide to Understanding Pain & Its Management*, American
22 Pain Foundation (2011) at
23 5, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>
(last visited March 6, 2018).

24 ²⁶³ See, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*,
25 Emerging Solutions in Pain http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

26 ²⁶⁴ Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012),
https://www.youtube.com/watch?v=_G3II9yqgXI.

27 ²⁶⁵ *Pain: Opioid Facts*,
28 http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patient/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited March 6, 2018).

1 downplayed the risk of addiction, even for people with a history of addiction
2 and opioid use, and supported the concept of pseudoaddiction.

3 519. Efforts to Criticize or Undermine CDC Guidelines – Members of the
4 Opioid Marketing Enterprise criticized or undermined the CDC Guidelines which
5 represented “an important step – and perhaps the first major step from the federal
6 government – toward limiting opioid prescriptions for chronic pain.” The following
7 are examples of the actions taken by Opioid Marketing Enterprise members to
8 prevent restriction on over-prescription:

- 9 • Several Front Groups, including the U.S. Pain Foundation, and the AAPM
10 criticized the draft guidelines in 2015, arguing that the “CDC slides presented
11 on Wednesday were not transparent relative to process and failed to disclose
12 the names, affiliation, and conflicts of interest of the individuals who
13 participated in the construction of these guidelines.”²⁶⁶
- 14 • The AAPM criticized the prescribing guidelines in 2016, through its
15 immediate past president, stating “that the CDC guideline makes
16 disproportionately strong recommendations based upon a narrowly selected
17 portion of the available clinical evidence.”²⁶⁷

18 520. In each of the actions performed by members of the Opioid Marketing
19 Enterprise, described above, the members of the Opioid Marketing Enterprise made
20 branded and unbranded marketing claims about prescription opioids that
21 misrepresented prescription opioids as non-addictive and safe for use as identified
22 in following section.

23
24
25 ²⁶⁶ Pat Anson, *Chronic Pain Group Blasts CDC for Opioid Guidelines*, Pain News
26 Networks, [https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-](https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines)
27 groups-blast-cdc-for-opioid-guidelines (last accessed on March 8, 2018).

28 ²⁶⁷ Practical Pain Management, Responses and Criticisms Over New CDC Opioid
Prescribing Guidelines
([https://www.practicalpainmanagement.com/resources/news-and-](https://www.practicalpainmanagement.com/resources/news-and-research/responses-criticisms-over-new-cdc-opioid-prescribing-guidelines)
research/responses-criticisms-over-new-cdc-opioid-prescribing-guidelines)
(accessed Sept. 28, 2017).

**4. Members of the Opioid Marketing Enterprise Furthered
the Common Purpose by Making Misrepresentations.**

521. The RICO Marketing Defendants, Front Groups and KOLs participated in the conduct of the Opioid Marketing Enterprise and shared in the common purpose of marketing opioids for chronic pain through a pattern of racketeering activity (including multiple instances of mail and wire fraud) by knowingly making material misrepresentations or omissions to California prescribers, consumers, the general public, regulators and The County. All of the misrepresentations made by members of the Opioid Marketing Enterprise furthered the common purpose of the Enterprise.

522. Members of the Opioid Marketing Enterprise, including the RICO Marketing Defendants, Front Groups and KOLs made multiple unbranded marketing misrepresentations about the benefits and risks of opioid use, in furtherance of the Opioid Marketing Enterprise's common purpose, as follows:

523. Members of the Opioid Marketing Enterprise minimized the risks of addiction and/or construed opioids as non-addictive:

- AAMP and APS endorsed the use of opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low.²⁶⁸
- "[O]pioids are safe and effective, and only in rare cases lead to addiction."²⁶⁹
- "[T]he risks of addiction are . . . small and can be managed."²⁷⁰

²⁶⁸ The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society, 13 Clinical J. Pain 6 (1997).

²⁶⁹ *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain Foundation), <https://www.help.senate.gov/imo/media/doc/Giglio.pdf>.

²⁷⁰ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

Medscape: Controversy surrounds both the undertreatment and overtreatment of pain. Overtreatment of pain obviously involves the fear of causing or perpetuating opioid drug dependency. What recommendations can you give to primary care physicians who are reluctant to prescribe opioids, either as adjuncts or primary agents for pain control, because of these fears?

Dr. Fishman: It used to be that when you had a patient with pain and you were worried about giving him or her a drug that may be abusable or may cause addiction, the safest thing to do was nothing, as though doing nothing would have no risks in and of itself. We know that the risks of addiction are there, but they are small and can be managed. The AAPM is going to be at the forefront, educating

- Represented that calling opioids “‘narcotics’ reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines.”²⁷¹
- “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”²⁷²

OPIOID ANALGESICS (NARCOTICS)

Opioid analgesics are another important class of medications that are very effective pain relievers. As mentioned before, they may also be called “narcotics.” Unfortunately, this term is used by law enforcement to refer to drugs that are abused. Cocaine and heroin are called narcotics even though they are very different kinds of drugs. Calling opioid analgesics “narcotics” reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines. In the pain treatment world, the word opioid is used when speaking about this class of medications.

- The risk of addiction is manageable for patients regardless of past abuse histories.²⁷³

²⁷¹ APF, *Treatment Options*, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed on March 8, 2018).

²⁷² Good Morning America (ABC television broadcast Aug. 30, 2010).

²⁷³ Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain, 10 J. Pain 113 (2009).

- 1 • “[T]he likelihood that the treatment of pain using an opioid drug which is
2 prescribed by a doctor will lead to addiction is extremely low.”²⁷⁴
- 3 • Patients might experience withdrawal symptoms associated with physical
4 dependence as the decrease their dose, “[b]ut unlike actual addicts, such
5 individuals, if they resume their opioid use, will only take enough medication
6 to alleviate their pain.”²⁷⁵
- 7 • The notion that “strong pain medication leads to addiction” is a “common
8 misconception.”²⁷⁶

SOME COMMON MISCONCEPTIONS ABOUT PAIN

Use of strong pain medication leads to addiction. Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit www.painsafe.org.

- 15
- 16 • “Addiction to an opioid would mean that your pain has gone away but you
17 still take the medicine regularly when you don’t need it for pain, maybe just
18 to escape your problems.”²⁷⁷

21 ²⁷⁴ Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*,
22 The Wall Street Journal (Dec. 17, 2012),
[https://www.wsj.com/articles/SB1000142412788732447830457817334265704460](https://www.wsj.com/articles/SB10001424127887324478304578173342657044604)
23 4.

24 ²⁷⁵ Brief Amici Curiae of American Pain Foundation, National Foundation for the
25 Treatment of Pain, and The Ohio Pain Initiative, in Support of
26 Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA
27 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002),
[https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-](https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf)
28 [howland-apf-amicus.pdf](https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf).

²⁷⁶ A Policymaker’s Guide to Understanding Pain & Its Management, American
Pain Foundation (2011) at 5, [http://s3.documentcloud.org/documents/277603/apf-](http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf)
[policymakers-guide.pdf](http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf) (last visited March 6, 2018).

²⁷⁷ Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral
Opioid Analgesics*, Endo Pharmaceuticals (2004),

How can I be sure I'm not addicted?

- ◆ Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
- ◆ Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

- Even for patients assessed to have a risk of abuse, “it does not mean that opioid use will become problematic or that opioids are contraindicated.”²⁷⁸

WILL I BECOME ADDICTED TO OPIOIDS?

This is a key issue for both you and your doctor to discuss. In general, people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted. However, patients who misuse or abuse opioids can become addicted to them, so openly discussing your concerns with your doctor is important. People who are addicted to opioids crave the “unusually happy” effect the drug has on them (a “buzz” or “high”) and will continue to use the drug even though it harms them.



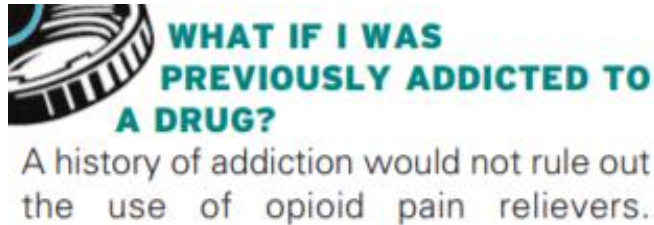
- [P]eople who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.”²⁷⁹

<https://www.yumpu.com/en/document/view/35479278/understanding-your-pain-taking-oral-opioid-analgesics> (last accessed March 8, 2018).

²⁷⁸ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, 8-9 (Waterford Life Sciences 2007).

²⁷⁹ *Pain: Opioid Facts*, <http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patie>

- “A history of addiction would not rule out the use of opioid pain relievers.”²⁸⁰



- APF published exit wounds, wherein it represented that “[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.”²⁸¹

Iraq War Veteran Amputee, Pain Advocate and New Author Releases Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families



"It's now four years since I lay in the dirt, near death, on the side of the road in Fallujah. I'm grateful for all the things I have, and proud of all I've accomplished. In the end though, I don't measure how far I've come by goals achieved, or academic degrees earned, or running trophies won. For me, what counts is that pain no longer rules my life." – Derek McGinnis

The American Pain Foundation (APF) announces the release of Iraq War Veteran and Pain Advocate Derek McGinnis' first book, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*. Written in collaboration with nationally renowned pain experts, the release date of September 21 for Exit Wounds coincided with September's designation as Pain Awareness Month.

- Patients rarely become addicted to prescribed opioids.²⁸²

nted/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited March 6, 2018).

²⁸⁰ *Id.*

²⁸¹ Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families, Coalition for Iraq + Afghanistan Veterans, <http://web.archive.org/web/20100308224011/http://coalitionforveterans.org:80/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families> (last visited March 1, 2018).

²⁸² Brief of Amici the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain, 2005 WL 2405247, *9 (citing Portenoy, Russell, et al., *Acute and Chronic Pain*, in *COMPREHENSIVE TEXTBOOK OF SUBSTANCE ABUSE*, 863-903 (Lowinson et al. eds., 4th ed. 2005), *United States v. Hurowitz*, 459 F.3d 463 (2006) (citing Portenoy et. al,

- Concern about patients becoming addicted reflects widespread failure to appreciate the distinction between “(1) *tolerance* – the body’s tendency to become accustomed to a substance so that, over time, a larger amount is needed to produce the same physical effect (pain relief) and *physical dependence* – the state defined by the experience of adverse symptoms if a drug is abruptly withdrawn . . . each of which is common with pain patients” . . . “and, on the other hand, (2) the psychological and behavioral patterns – an unhealthy craving for, compulsive use of, and unhealthy fixation – that characterize *addiction*.”²⁸³
- Evidence establishes that the risk of drug addiction (historically the principal *medical* justification for withholding or limiting opioids) is far *less* substantial than long and widely assumed.²⁸⁴

the addiction. Although the risks are exceedingly low in older patients with no current or past history of substance abuse, it is impossible to identify every patient who will abuse or divert prescribed opioids.¹¹⁷ Therefore, many clinicians have adopted a Universal Precautions approach to pain management.¹¹⁸ This paradigm stresses that every pa-

- The “risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.”²⁸⁵

Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases, PAIN, Vol. 25, 171-186, (1986)).

²⁸³ Brief of Amici Russel K. Portenoy, *et al.*, 2005 WL 2405249, *United States v. Hurwitz*, 459 F.3d 463 (2006) (emphasis in original).

²⁸⁴ *Id.* and sources cited at note 9.

²⁸⁵ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).

524. Members of the Opioid Marketing Enterprise advocated that opioids were safe and effective for long-term treatment of chronic, non-acute and non-cancer pain:

- “Opioids are an essential option for treating *moderate* to severe pain associated with surgery or trauma. They may also be an important part of the management of persistent pain unrelated to cancer.”²⁸⁶

Clinical uses

Opioids are an essential option for treating moderate to severe pain associated with surgery or trauma, and for pain related to cancer. They may also be an important part of the management of persistent pain unrelated to cancer. These medicines block pain

- Opioids were a safe and effective treatment for of pain as part of a physicians’ treatment guidelines.²⁸⁷
- The “small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients.”²⁸⁸
- Opioids, unlike some non-prescription pain medications, are safe at high doses.²⁸⁹
- Falsely representing “recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems.”²⁹⁰

²⁸⁶ APF, *Treatment Options*, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

²⁸⁷ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

²⁸⁸ Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

²⁸⁹ Portenoy, et al., *Overview of Management Options*, <https://cme.ama-assn.org/activity/1296783/detail.aspx>. On information and belief, this CME was published in 2003, 2007, 2010, and 2013.

²⁹⁰ *Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0-SF*, PainEdu.org, 2008, <https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf> (last accessed on March 8, 2018).

- 1 • Opioid therapy is an appropriate treatment for chronic, non-cancer pain and
2 integral to good medical practice.²⁹¹
- 3 • Even for patients assessed to have a risk of abuse, “it does not mean that
4 opioid use will become problematic or that opioids are contraindicated.”²⁹²
- 5 • Opioid therapy is an appropriate treatment for chronic, non-cancer pain and
6 integral to good medical practice.²⁹³
- 7 • Broadly classifying pain syndromes as “either cancer- or non-cancer-related
8 has limited utility,” and recommended dispensing rapid onset opioids “in
9 patients with non-cancer pain.”²⁹⁴

10 The data suggest that FEBT is safe and well tolerated in opioid-tolerant patients
11 with chronic noncancer pain. There was no respiratory depression, and a low
12 incidence of treatment-related adverse events was reported. Thirty-five patients
13 (37%) reported having at least 1 adverse event, the most common of which were
nausea (7%) and dizziness (5%).

- 14 • Opioids are safe and well-tolerated in patients with chronic pain and break
15 through pain.²⁹⁵

20 ²⁹¹ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9
(Waterford Life Sciences 2007).

21 ²⁹² *Id.*

22 ²⁹³ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9 (Waterford Life
23 Sciences 2007).

24 ²⁹⁴ Perry G Fine, MD, et al. *Opioid-Based Management of Persistent and*
Breakthrough Pain, Pain Medicine News,
25 [https://www.yumpu.com/en/document/view/11409251/opioid-based-management-](https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain)
of-persistent-and-breakthrough-pain (accessed on February 27, 2018).

26 ²⁹⁵ Hale ME, Webster LR, Peppin JF, Messina J. Open-label study of fentanyl
27 effervescent buccal tablets in patients with chronic pain and breakthrough pain:
interim safety and tolerability results. Program and abstracts of the annual meeting
28 of the American Academy of Pain Medicine; February 22-25, 2006; San Diego,
California. Abstract 120. Published with permission of Lynn R. Webster, MD,
https://www.medscape.org/viewarticle/524538_2 (accessed on March 6, 2018).

- Non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective than opioids because of dose limitations on non-opioids.²⁹⁶

adverse events. Furthermore, although nonopioid analgesics, such as acetaminophen and NSAIDs/COX-2 inhibitors, are effective for nociceptive pain, their use in BTP is likewise restricted by dose-limiting toxicities, an onset of action that is delayed by 30 minutes or more, a long duration of action that could augment sedation and other side effects of the agent used for the baseline pain, and fears about renal and cardiovascular complications. Agents that combine an SAO, such as hydrocodone plus acetaminophen, aspirin, or ibuprofen, also are limited by potential adverse events and ceiling effects from the nonopioid component.

- Opioids can safely alleviate chronic pain unresponsive to other medication.²⁹⁷
- Medical organization and government-sponsored clinical guidelines support and encourage opioid treatment for chronic pain.²⁹⁸
- Respiratory depression, even at extremely high levels, does not occur in the context of appropriate clinical treatment.²⁹⁹
- There is no “ceiling dose” for opioids.³⁰⁰
- Opioid analgesics are the most effective way to treat pain of moderate to severe intensity and often the only treatment that provides significant relief.³⁰¹

²⁹⁶ Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, http://www.medscape.org/viewarticle/563417_6 (last visited Dec. 11, 2017).

²⁹⁷ Brief of Amici the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain, 2005 WL 2405247, *8, *United States v. Hurowitz*, 459 F.3d 463 (2006) (citing Portenoy et. al, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, PAIN, Vol. 25, 171-186, (1986)).

²⁹⁸ *Id.* at *8, and sources cited in note 11.

²⁹⁹ *Id.*

³⁰⁰ *Id.*

³⁰¹ Brief of Amici Russel K. Portenoy, et al., 2005 WL 2405249, *United States v. Hurwitz*, 459 F.3d 463.

- “Opioid rotations” (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, may need to occur four or five times over a person’s “lifetime” to manage pain.³⁰²
- Opioids represent a highly effective . . . class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.³⁰³

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids—the gradual waning of relief at a given dose—and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.³

525. Members of the Opioid Marketing Enterprise created and championed the concept of “pseudoaddiction,” advocating that signs of addiction were actually pseudoaddiction that required prescribing additional opioids:

- Patients might experience withdrawal symptoms associated with physical dependence as the decrease their dose, “[b]ut unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain.”³⁰⁴

³⁰² Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

³⁰³ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, 2007, https://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last visited on March 8, 2018).

³⁰⁴ Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002),

- 1 • “Addiction **IS NOT** when a person develops ‘withdrawal’ (such as
2 abdominal cramping or sweating) after the medicine is stopped or the dose is
3 reduced by a large amount. . . . Addiction also **IS NOT** what happens when
4 some people taking opioids need to take a higher dose after a period of time
5 in order for it to continue to relieve their pain. This normal ‘tolerance’ to
6 opioid medications doesn’t affect everyone who takes them and does not, by
7 itself, imply addiction.”³⁰⁵

8 **WHAT SHOULD I KNOW ABOUT** 9 **OPIOIDS AND ADDICTION?**

10 You or your family may have questions about
11 addiction. It is important to understand what
12 addiction is. Addiction **IS** a chronic brain dis-
13 ease that can occur in some people exposed
14 to certain substances such as alcohol,
15 cocaine, and opioids. Taking opioids for pain
16 relief is not addiction. People addicted to opi-
17 oids crave the opioid and use it regularly for
18 reasons other than pain relief.

19 Addiction **IS NOT** when a person develops
20 "withdrawal" (such as abdominal cramping
21 or sweating) after the medicine is stopped
22 quickly or the dose is reduced by a large
23 amount. Your doctor will avoid stopping your
24 medication suddenly by slowly reducing the
25 amount of opioid you take before the medi-
26 cine is completely stopped. Addiction also
27 **IS NOT** what happens when some people
28 taking opioids need to take a higher dose
after a period of time in order for it to contin-
ue to relieve their pain. This normal "toler-
ance" to opioid medications doesn't affect
everyone who takes them and does not, by
itself, imply addiction. If tolerance does
occur, it does not mean you will "run out" of
pain relief. Your dose can be adjusted or
another medicine can be prescribed.

27 <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

28 ³⁰⁵ Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004),

- “Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don’t need it for pain, maybe just to escape your problems.”³⁰⁶

How can I be sure I’m not addicted?

- ◆ Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don’t need it for pain, maybe just to escape from your problems.
- ◆ Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

- Behaviors such as “[r]equesting [drugs] by name,” “[d]emanding or manipulative behavior,” “[o]btaining drugs from more than one physician,” and “[h]oarding opioids,” are all really signs of pseudoaddiction, rather than genuine addiction.”³⁰⁷
- “Sometimes people behave as if they are addicted, when they are really in need of more medication.”³⁰⁸

http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf (emphasis in original) (last accessed on March 9, 2018).

³⁰⁶ *Id.*

³⁰⁷ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9 (Waterford Life Sciences 2007).

³⁰⁸ *Pain: Opioid Facts*, http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patient/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited March 6, 2018).

- **ADDICTION** - A craving that drives a person to take an opioid even though it causes harm. This is a problem that needs immediate treatment. This happens to some patients who use opioids.

Sometimes people behave as if they are addicted, when they are really in need of more medication. This can be treated with higher doses of medicine.

- For prescribers facing signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”³⁰⁹

526. Members of the Opioid Marketing Enterprise advocated that long-term use of prescription opioids would improve function, including but not limited to, psychological health, and health-related quality of life:

Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain¹²

³⁰⁹ Lynn Webster & Beth Dove, Avoiding Opioid Abuse While Managing Pain (2007).

- 1 • When opioids are managed, properly prescribed and taken as directed, they
2 are effective in improving daily function, psychological health and health-
3 related quality of life.³¹⁰
- 4 • Opioid therapy to relieve pain and improve function is a legitimate medical
5 practice for acute and chronic pain of both cancer and non-cancer origins.³¹¹
- 6 • “[Y]our level of function should improve, you may find you are now able to
7 participate in activities of daily living, such as work and hobbies, that you
8 were not able to enjoy when your pain was worse.”³¹²
- 9 • “The goal of opioid therapy is to . . . improve your function.”³¹³

10 ***The goal of opioid therapy is to control pain and improve your function.***
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21 ³¹⁰ A Policymaker’s Guide to Understanding Pain & Its Management, American
22 Pain Foundation (2011) at

23 5, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>
(last visited March 6, 2018).

24 ³¹¹ Scott M. Fishman, Responsible Opioid Prescribing: A Physician’s Guide, 8-9
25 (Waterford Life Sciences 2007); Scott M. Fishman, *Responsible Opioid*
Prescribing: A Clinician’s Guide, 10-11 (2d ed. 2012).

26 ³¹² Plaintiffs are informed and believe that this misrepresentation was made on the
website [painknowledge.org](http://www.painknowledge.org).

27 ³¹³ *Pain: Opioid Facts*,
28 http://web.archive.org/web/20120112051109/http://www.painknowledge.org/patient/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last
visited March 6, 2018).

- The “goal” for chronic pain patients is to “improve effectiveness which is different from efficacy and safety.”³¹⁴



527. Members of the Opioid Marketing Enterprise represented that screening questions and professional guidelines would help curb addiction and potential abuse:

- Screening questions and professional guidelines will “easily and efficiently” allow physicians to manage risk and “minimize the potential for abuse.”³¹⁵
- Risk screening tools, urine testing, and patient agreements are a way to prevent “overuse of prescriptions” and “overdose deaths.”³¹⁶

³¹⁴ Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

³¹⁵ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8-9 (Waterford Life Sciences 2007).

³¹⁶ See, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*, Emerging Solutions in Pain http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

Program Overview

Compliance with regulatory and policy-driven authorities mandates improvement in the treatment of patients on chronic opioid therapy (COT) to ensure that the best possible care is provided to pain patients while minimizing potential risk of inappropriate use. Participants of this activity will be able to evaluate current issues in appropriate patient selection and management of chronic pain patients treated with COT including a review of the most current Risk Evaluation and Mitigation Strategies (REMS) requirements, updates in the development of novel delivery systems and the practical application of assessment tools to assist in their daily practice.

- The risks of addiction and abuse can be managed by doctors and evaluated with “tools.”³¹⁷

528. In addition to the unbranded marketing misrepresentations made by members of the Opioid Marketing Enterprise, the RICO Marketing Defendants made misrepresentations in their branded marketing activities. The RICO Marketing Defendants’ branded marketing misrepresentations furthered the common purpose of the Opioid Marketing Enterprise because they advanced the common messages of the Opioid Marketing Enterprise. For example:

529. The RICO Marketing Defendants misrepresented that opioids were non-addictive or posed less risk of addiction or abuse:

- Purdue:
 - “Fear of addiction is exaggerated.”³¹⁸

³¹⁷ Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

³¹⁸ Harriet Ryan, et al., “*You Want A Description of Hell?*” *OxyContin’s 12-Hour Problem*, L.A. Times (May 5, 2016), <http://documents.latimes.com/oxycontin-press-release-1996/> (hereinafter “Ryan, Description of Hell”).

The fear of addiction is exaggerated.
One cause of patient resistance to appropriate pain treatment – the fear of addiction – is largely unfounded. According to Dr. Max, "Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient's need, and that there is very little risk of addiction from the proper uses of these drugs for pain relief."

Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma** L.P. in Norwalk, Connecticut, agrees with this assessment. "Proper use of medication is an essential weapon in the battle against persistent pain. But too often fear, misinformation and poor communication stand in the way of their legitimate use."

- "[W]e've discovered that the simplicity and convenience of twice-daily dosing also enhances patient compliance with their doctor's instructions."³¹⁹

taking tablets every four to six hours. Moreover, we've discovered that the simplicity and convenience of twice-daily dosing also enhances

https://www.nexis.com/results/enhdocview.do?docLinkInd=true&ersKey=23_T23962617276&format=GNBF

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patient compliance with their doctor's instructions."

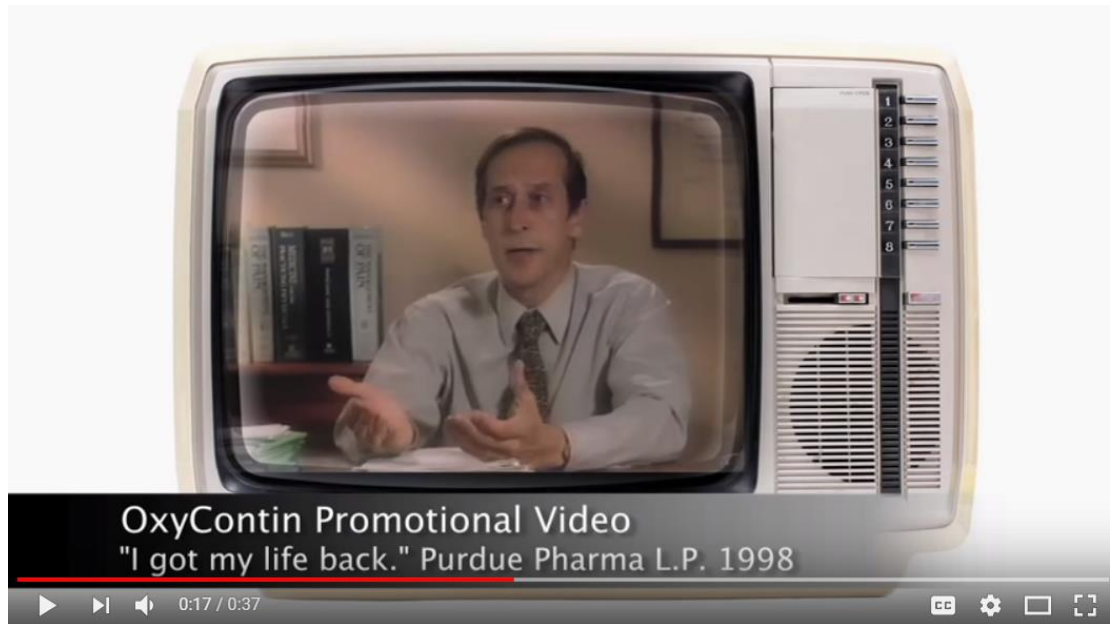
- Long-acting, extended release formulations are safe and "less prone" to abuse by patients and addiction.³²⁰
- OxyContin is safe and non-addictive when using extended release formulations, and appropriate for use in non-cancer patients.³²¹

³¹⁹ *Id.*

³²⁰ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. Times (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html> (hereinafter "Meier, Guilty Plea").

³²¹ Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), http://www.opb.org/news/article/america_pain_foundation_shuts_down_as_senato

- Consistently minimizing the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain.³²²
- OxyContin is virtually non-addicting.³²³
- “Assur[ing] doctors – repeatedly and without evidence – that ‘fewer than one percent’ of patients who took OxyContin became addicted.”³²⁴



- OxyContin was addiction resistant and had “abuse-deterrent properties.”³²⁵

rs_launch investigation of prescription_narcotis/ (hereinafter “Ornstein, *American Pain Foundation*”).

³²² Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph*, Public Health Tragedy, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009) (hereinafter, “Van Zee, Promotion and Marketing”).

³²³ Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>

³²⁴ *Id.*; see also “I got my life back,” OxyContin Promotional Video, 1998, <https://www.youtube.com/watch?v=Er78Dj5hyeI> (last accessed on March 8, 2018).

³²⁵ *Id.*

- Misrepresented the risk of addiction using misleading and inaccurate promotions of OxyContin that were unsupported by science.³²⁶
- It was more difficult to extract the oxycodone from an OxyContin tablet for intravenous abuse.³²⁷
- OxyContin created fewer chances for addiction than immediate-release opioids.³²⁸
- OxyContin had fewer “peak and trough” effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.³²⁹
- Patients could abruptly stop opioid therapy without experiencing withdrawal symptoms, and patients who took OxyContin would not develop tolerance.³³⁰
- OxyContin did not cause a “buzz,” caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to “weed out” addicts and drug seekers.³³¹
- Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, “Indications of Possible Drug Abuse,” shows pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who

³²⁶ Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), <https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf>.

³²⁷ *Id.*

³²⁸ *Id.*

³²⁹ *Id.*

³³⁰ *Id.*

³³¹ *Id.*

resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these misrepresentations wrongly reassured doctors that as long as they do not observe those signs, they need not worry that their patients are abusing or addicted to opioids.

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication is still available online. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction."
- Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.
- A Purdue-funded study with a Purdue co-author claimed that "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."³³² The study relied only on the 1980 Porter-Jick letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. Although the term "low" is not defined, the overall presentation suggests the risk is so low as not to be a worry.
- Purdue contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past

³³² C. Peter N. Watson et al., Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy, 105 *Pain* 71 (2003).

1 history of substance abuse.” None of the references in the guidelines
 2 corroborates the claim that elderly patients are less likely to become
 3 addicted to opioids and the claim is, in fact, untrue. Purdue was aware
 4 of the AGS guidelines’ content when it agreed to provide this funding,
 5 and AGS drafted the guidelines with the expectation it would seek drug
 6 company funding to promote them after their completion.

- 7 ○ Purdue sponsored APF’s *Exit Wounds* (2009), which counseled
 8 veterans that “[l]ong experience with opioids shows that people who
 9 are not predisposed to addiction are very unlikely to become addicted
 10 to opioid pain medications.” Although the term “very unlikely” is not
 11 defined, the overall presentation suggests it is so low as not to be a
 12 worry.
- 13 ○ Purdue sales representatives told prescribers that its drugs were
 14 “steady state,” the implication of which was that they did not produce
 15 a rush or euphoric effect, and therefore were less addictive and less
 16 likely to be abused.
- 17 ○ Purdue sales representatives told prescribers that Butrans has a lower
 18 abuse potential than other drugs because it was essentially tamperproof
 19 and, after a certain point, patients no longer experience a “buzz” from
 20 increased dosage.
- 21 ○ Advertisements that Purdue sent to prescribers stated that OxyContin
 22 ER was less likely to be favored by addicts, and, therefore, less likely
 23 to be abused or diverted, or result in addiction.
- 24 ○ In discussions with prescribers, Purdue sales representatives omitted
 25 discussion of addiction risks related to Purdue’s drugs.
- 26 ● Janssen:
- 27 ○ **Myth:** Opioid medications are always addictive.
- 28

Fact: Many studies show that opioids are rarely addictive when used properly for the management of chronic pain.³³³

- **Myth:** Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.³³⁴

- “[Q]uestions of addiction,” “are often overestimated” because, “[a]ccording to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics.”³³⁵

Other Opioid Analgesic Concerns

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.^{15,16} By the same token, patients report similar concerns about developing an addiction to opioid analgesics.¹⁷ While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesic therapy.¹⁸

- Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a “myth” that opioids are addictive, and asserts as fact that “[m]any studies show that opioids are rarely addictive when used

³³³ Finding Relief, Pain Management for Older Adults, (2009) (emphasis in original).

³³⁴ Finding Relief, Pain Management for Older Adults, (2009) (emphasis in original).

³³⁵ *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Dec. 11, 2017).

1 properly for the management of chronic pain.” Although the term
2 “rarely” is not defined, the overall presentation suggests the risk is so
3 low as not to be a worry. The language also implies that as long as a
4 prescription is given, opioid use is not a problem.

- 5 ○ Janssen contracted with AGS to produce a CME promoting the 2009
6 guidelines for the *Pharmacological Management of Persistent Pain in*
7 *Older Persons*. These guidelines falsely claim that “the risks [of
8 addiction] are exceedingly low in older patients with no current or past
9 history of substance abuse.” The study supporting this assertion does
10 not analyze addiction rates by age and, as already noted, addiction
11 remains a significant risk for elderly patients. Janssen was aware of the
12 AGS guidelines’ content when it agreed to provide this funding, and
13 AGS drafted the guidelines with the expectation it would seek drug
14 company funding to promote them after their completion.
- 15 ○ Janssen provided grants to APF to distribute *Exit Wounds* (2009) to
16 veterans, which taught that [l]ong experience with opioids shows that
17 people who are not predisposed to addiction are very unlikely to
18 become addicted to opioid pain medications.” Although the term “very
19 unlikely” is not defined, the overall presentation suggests the risk is so
20 low as not to be a worry.
- 21 ○ Janssen currently runs a website, Prescriberresponsibly.com (last
22 modified July 2, 2015), which claims that concerns about opioid
23 addiction are “overstated.”
- 24 ○ A June 2009 Nucynta Training module warns Janssen’s sales force that
25 physicians are reluctant to prescribe controlled substances like
26 Nucynta, but this reluctance is unfounded because “the risks . . . are
27 much smaller than commonly believed.”
28

- Janssen sales representatives told prescribers that its drugs were “steady state,” the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.
- Janssen sales representatives told prescribers that Nucynta and Nucynta ER were “not opioids,” implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen’s drugs. In truth, however, as set out in Nucynta’s FDA-mandated label, Nucynta “contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit.”
- Janssen’s sales representatives told prescribers that Nucynta’s unique properties eliminated the risk of addiction associated with the drug.
- In discussions with prescribers, Janssen sales representatives omitted discussion of addiction risks related to Janssen’s drugs.
- Cephalon:
 - Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient’s Guide*, which claims, among other things, that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.”
 - Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.
 - In discussions with prescribers, Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon’s drugs.
- Endo:

- 1 ○ Opana ER was designed to be crush resistant
- 2 ○ Opana ER was crush and abuse resistant and not addictive.³³⁶
- 3 ○ “[T]he Reformulated Opana ER as ‘designed to be’ crush resistant.”³³⁷
- 4 ○ “[P]atients treated with prolonged opioid medicines usually do not
- 5 become addicted.”³³⁸
- 6 ○ Endo trained its sales force in 2012 that use of long-acting opioids
- 7 resulted in increased patient compliance, without any supporting
- 8 evidence.
- 9 ○ Endo’s advertisements for the 2012 reformulation of Opana ER
- 10 claimed it was designed to be crush resistant, in a way that conveyed
- 11 that it was less likely to be abused. This claim was false; the FDA
- 12 warned in a May 10, 2013 letter that there was no evidence Endo’s
- 13 design “would provide a reduction in oral, intranasal or intravenous
- 14 abuse” and Endo’s “post-marketing data submitted are insufficient to
- 15 support any conclusion about the overall or route-specific rates of
- 16 abuse.” Further, Endo instructed its sales representatives to repeat this
- 17 claim about “design,” with the intention of conveying Opana ER was
- 18 less subject to abuse.
- 19 ○ Endo sponsored a website, painknowledge.com, through APF and
- 20 NIPC, which claimed in 2009 that: “[p]eople who take opioids as
- 21 prescribed usually do not become addicted.” Although the term
- 22
- 23

24 ³³⁶ *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*,
 25 Assurance No. 15-228, Assurance of Discontinuance Under Executive Law
 26 Section 63, Subdivision 15, at 5 (Mar. 1, 2016),
https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

27 ³³⁷ *Id.* at 6.

28 ³³⁸ *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*,
 Assurance No. 15-228, Assurance of Discontinuance Under Executive Law
 Section 63, Subdivision 15, at 5 (Mar. 1, 2016),
https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

1 “usually” is not defined, the overall presentation suggests the risk is so
 2 low as not to be a worry. The language also implies that as long as a
 3 prescription is given, opioid use will not become problematic. Endo
 4 continued to provide funding for this website through 2012, and
 5 closely tracked unique visitors to it.

- 6 ○ Endo sponsored a website, PainAction.com, which stated “Did you
 7 know? Most chronic pain patients do not become addicted to the opioid
 8 medications that are prescribed for them.”
- 9 ○ Endo sponsored CMEs published by APF’s NIPC, of which Endo was
 10 the sole funder, titled *Persistent Pain in the Older Adult and Persistent*
 11 *Pain in the Older Patient*. These CMEs claimed that opioids used by
 12 elderly patients present “possibly less potential for abuse than in
 13 younger patients[,]” which lacks evidentiary support and deceptively
 14 minimizes the risk of addiction for elderly patients.
- 15 ○ Endo distributed an education pamphlet with the Endo logo titled
 16 *Living with Someone with Chronic Pain*, which inaccurately
 17 minimized the risk of addiction: “Most health care providers who treat
 18 people with pain agree that most people do not develop an addiction
 19 problem.”
- 20 ○ Endo distributed a patient education pamphlet edited by key opinion
 21 leader Dr. Russell Portenoy titled *Understanding Your Pain: Taking*
 22 *Oral Opioid Analgesics*. It claimed that “[a]ddicts take opioids for
 23 other reasons [than pain relief], such as unbearable emotional
 24 problems.” This implies that pain patients prescribed opioids will not
 25 become addicted, which is unsupported and untrue.
- 26 ○ Endo contracted with AGS to produce a CME promoting the 2009
 27 guidelines for the *Pharmacological Management of Persistent Pain in*
 28

1 *Older Persons*. These guidelines falsely claim that “the risks [of
 2 addiction] are exceedingly low in older patients with no current or past
 3 history of substance abuse.” None of the references in the guidelines
 4 corroborates the claim that elderly patients are less likely to become
 5 addicted to opioids, and there is no such evidence. Endo was aware of
 6 the AGS guidelines’ content when it agreed to provide this funding,
 7 and AGS drafted the guidelines with the expectation it would seek drug
 8 company funding to promote them after their completion.

- 9 ○ Endo sales representatives told prescribers that its drugs were “steady
 10 state,” the implication of which was that they did not produce a rush
 11 or euphoric effect, and therefore were less addictive and less likely to
 12 be abused.
- 13 ○ Endo provided grants to APF to distribute *Exit Wounds* (2009) to
 14 veterans, which taught that “[l]ong experience with opioids shows that
 15 people who are not predisposed to addiction are very unlikely to
 16 become addicted to opioid pain medications.” Although the term “very
 17 unlikely” is not defined, the overall presentation suggests that the risk
 18 is so low as not to be a worry.
- 19 ○ In discussions with prescribers, Endo sales representatives omitted
 20 discussion of addiction risks related to Endo’s drugs.

21 530. The RICO Marketing Defendants misrepresented that opioids
 22 improved function and quality of life:

- 23 • Purdue:

- 1 ○ “[W]e’ve discovered that the simplicity and convenience of twice-
- 2 daily dosing also enhances patient compliance with their doctor’s
- 3 instructions.”³³⁹

4

5 taking tablets every four to six hours. Moreover, we’ve discovered that

6 the simplicity and convenience of twice-daily dosing also enhances

7 https://www.nexis.com/results/enhdocview.do?docLinkInd=true&ersKey=23_T23962617276&format=GNBF

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10 patient compliance with their doctor’s instructions.”

- 11 ○ Purdue ran a series of advertisements for OxyContin in 2012 in
- 12 medical journals titled “Pain vignettes,” which were case studies
- 13 featuring patients, each with pain conditions persisting over several
- 14 months, recommending OxyContin for each. One such patient, “Paul,”
- 15 is described to be a “54-year-old writer with osteoarthritis of the
- 16 hands,” and the vignettes imply that an OxyContin prescription will
- 17 help him work more effectively.
- 18 ○ Purdue sponsored APF’s *A Policymaker’s Guide to Understanding*
- 19 *Pain & Its Management*, which inaccurately claimed that “multiple
- 20 clinical studies” have shown that opioids are effective in improving
- 21 daily function, psychological health, and health-related quality of life
- 22 for chronic pain patients.” The sole reference for the functional
- 23 improvement claim noted the absence of long-term studies and
- 24 actually stated: “For functional outcomes, the other analgesics were
- 25 significantly more effective than were opioids.” *The Policymaker’s*
- 26 *Guide* is still available online.

27

28 ³³⁹ Ryan, *Description of Hell*, <http://documents.latimes.com/oxycontin-press-release-1996/>

- Purdue sponsored APF’s Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids, when used properly, “give [pain patients] a quality of life we deserve.” APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the guide currently is available online.
- Purdue sponsored APF’s *Exit Wounds* (2009), which taught veterans that opioid medications “increase your level of functioning.” *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.
- Purdue sponsored the FSMB’s Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients’ function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a “long-term therapeutic treatment course.” Purdue also spent over \$100,000 to support distribution of the book.
- Janssen:
 - Misrepresented that patients experienced “[s]ignificantly reduced nighttime awakenings.”³⁴⁰
 - Misrepresented “[s]ignificant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index.”³⁴¹
 - Misrepresented “[s]ignificant improvement in social functioning.”

³⁴⁰ NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

³⁴¹ *Id.*

- Misrepresented outcome claims that were misleading because they lacked substantial support, evidence or clinical experience and “impl[ied] that patients will experience improved social or physical functioning or improved work productivity when using Duragesic,” including: “1,360 loaves . . . and counting, [w]ork, uninterrupted, [l]ife, uninterrupted, [g]ame, uninterrupted, [c]hronic pain relief that supports functionality, [h]elps patients think less about their pain, and [i]mprove[s] . . . physical and social functioning.”³⁴²
- Misrepresented that “[o]pioid analgesics, for example, have no true ‘ceiling dose’ for analgesia and do not cause direct organ damage.”³⁴³

Use of Opioid Analgesics in Pain Management

Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true “ceiling dose” for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.⁸

- **Myth:** Opioids make it harder to function normally.
Fact: When used correctly for appropriate conditions, opioids may make it easier for people to live normally.³⁴⁴
- Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional

³⁴² *Id.* at 3 (internal quotations omitted).

³⁴³ *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Dec. 11, 2017).

³⁴⁴ *Finding Relief, Pain Management for Older Adults*, (2009) (emphasis in original).

improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a “fact” that “opioids may make it easier for people to live normally” (emphasis in the original). The myth/fact structure implies authoritative backing for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.

- Janssen sponsored, developed, and approved content of a website, *Let’s Talk Pain* in 2009, acting in conjunction with the APF and AAPM whose participation in Let’s Talk Pain Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to function,” inaccurately implying her experience would be representative. This video is still available today on youtube.com.
- Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications “increase your level of functioning” (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.
- Cephalon:
 - Cephalon sponsored the FSMB’s Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients’ function. Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a “long-term therapeutic treatment course.” Cephalon also spent \$150,000 to purchase copies of

the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

- Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids when used properly "give [pain patients] a quality of life we deserve." The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the publication is currently available online.
- Cephalon sponsored a CME written by Dr. Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids.
- Endo:
 - Opana ER "will benefit patients, physicians and payers."³⁴⁵
 "Patient safety is our top concern and addressing appropriate use of opioids is a responsibility that we take very seriously. We firmly believe this new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."
 - "Endo distributed a pamphlet in New York and posted on its public website, www.opana.com, photographs of purported Opana ER

³⁴⁵ *FDA Approves Endo Pharmaceuticals' Crush-Resistant Opana ER*, December 12, 2011, <https://www.biospace.com/article/releases/fda-approves-endo-pharmaceuticals-crush-resistant-opana-er/>.

1 patients that implied that patients can achieve higher function with
 2 Opana ER.”³⁴⁶

- 3 ○ Endo sponsored a website, painknowledge.com, through APF and
 4 NIPC, which claimed in 2009 that with opioids, “your level of function
 5 should improve; you may find you are now able to participate in
 6 activities of daily living, such as work and hobbies, that you were not
 7 able to enjoy when your pain was worse.” Endo continued to provide
 8 funding for this website through 2012, and closely tracked unique
 9 visitors to it.
- 10 ○ A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*,
 11 taught that chronic opioid therapy has been “shown to reduce pain and
 12 improve depressive symptoms and cognitive functioning.”
- 13 ○ Endo distributed handouts to prescribers that claimed that use of Opana
 14 ER to treat chronic pain would allow patients to perform work as a
 15 chef. This flyer also emphasized Opana ER’s indication without
 16 including equally prominent disclosure of the “moderate to severe
 17 pain” qualification.
- 18 ○ Endo’s sales force distributed FSMB’s *Responsible Opioid*
 19 *Prescribing* (2007). This book taught that relief of pain itself improved
 20 patients’ function. Responsible Opioid Prescribing explicitly describes
 21 functional improvement as the goal of a “long-term therapeutic
 22 treatment course.”
- 23 ○ Endo provided grants to APF to distribute *Exit Wounds* to veterans,
 24 which taught that opioid medications “increase your level of
 25 functioning” (emphasis in the original). Exit Wounds also omits
 26 warnings of the risk of interactions between opioids and
 27

28 ³⁴⁶ *Id.* at 8.

1 benzodiazepines, which would increase fatality risk. Benzodiazepines
 2 are frequently prescribed to veterans diagnosed with post-traumatic
 3 stress disorder.

4 531. The RICO Marketing Defendants misrepresented that addiction risks
 5 can be avoided or managed through screening tools and prescription guidelines:

6 • Purdue:

- 7 ○ Purdue's unbranded website, In the Face of Pain
 8 (inthefaceofpain.com) states that policies that "restrict[]" access to
 9 patients with pain who also have a history of substance abuse" and
 10 "requiring special government-issued prescription forms for the only
 11 medications that are capable of relieving pain that is severe" are "at
 12 odds with" best medical practices.³⁴⁷
- 13 ○ Purdue sponsored a 2012 CME program taught by a KOL titled
 14 *Chronic Pain Management and Opioid Use: Easing Fears, Managing*
 15 *Risks, and Improving Outcomes*. This presentation recommended that
 16 use of screening tools, more frequent refills, and switching opioids
 17 could treat a high-risk patient showing signs of potentially addictive
 18 behavior.
- 19 ○ Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, titled
 20 *Managing Patient's Opioid Use: Balancing the Need and Risk*. This
 21 publication taught prescribers that screening tools, urine tests, and
 22 patient agreements have the effect of preventing "overuse of
 23 prescriptions" and "overdose deaths."
- 24

25
 26
 27 ³⁴⁷ See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment, Purdue
 28 Pharma L.P. (Resources verified Mar. 2012),
www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf
 f.

- Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction.
- Cephalon:
 - Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that “opioid agreements” between doctors and patients can “ensure that you take the opioid as prescribed.”
- Endo:
 - Endo paid for a 2007 supplement³⁴⁸ available for continuing education credit in the Journal of Family Practice and written by a doctor who later became a member of Endo’s speakers bureau. This publication, titled *Pain Management Dilemmas in Primary Care: Use of Opioids*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely (e.g., without becoming addicted) receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts.

532. The RICO Marketing Defendants misrepresented that signs of opioid addiction were not addiction, withdrawal could be simply managed, and promoted the concept of pseudoaddiction:

- Purdue:
 - Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which

³⁴⁸ The Medical Journal, The Lancet found that all of the supplement papers it received failed peer-review. Editorial, “*The Perils of Journal and Supplement Publishing*,” 375 The Lancet 9712 (347) 2010.

described pseudoaddiction as a concept that “emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated.”

- Purdue distributed to physicians, at least as of November 2006 and posted on its unbranded website, Partners Against Pain, a pamphlet copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct including “illicit drug use and deception” it defined as indicative of pseudoaddiction or untreated pain. It also states: “Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. . . . Even such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.”
- Purdue sponsored FSMB’s *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name, “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. Purdue also spent over \$100,000 to support distribution of the book.
- Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which states: “Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.”
- *A Policymaker’s Guide to Understanding Pain & Its Management* also taught that “Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during

1 discontinuation,” but did not disclose the significant hardships that
2 often accompany cessation of use.

- 3 ○ Purdue sales representatives told prescribers that the effects of
4 withdrawal from opioid use can be successfully managed.
5 ○ Purdue sales representatives told prescribers that the potential for
6 withdrawal on Butrans was low due to Butrans’ low potency and its
7 extended release mechanism.

8 ● Janssen:

- 9 ○ Janssen’s website, Let’s Talk Pain, stated from 2009 through 2011 that
10 “pseudoaddiction . . . refers to patient behaviors that may occur when
11 pain is under-treated” and “[p]seudoaddiction is different from true
12 addiction because such behaviors can be resolved with effective pain
13 management.”
14 ○ A Janssen PowerPoint presentation used for training its sales
15 representatives titled “*Selling Nucynta ER*” indicates that the “low
16 incidence of withdrawal symptoms” is a “core message” for its sales
17 force. This message is repeated in numerous Janssen training materials
18 between 2009 and 2011. The studies supporting this claim did not
19 describe withdrawal symptoms in patients taking Nucynta ER beyond
20 90 days or at high doses and would therefore not be representative of
21 withdrawal symptoms in the chronic pain population. Patients on
22 opioid therapy long-term and at high doses will have a harder time
23 discontinuing the drugs and are more likely to experience withdrawal
24 symptoms. In addition, in claiming a low rate of withdrawal
25 symptoms, Janssen relied upon a study that only began tracking
26 withdrawal symptoms in patients two to four days after discontinuing
27 opioid use, when Janssen knew or should have known that these
28

1 symptoms peak earlier than that for most patients. Relying on data after
 2 that initial window painted a misleading picture of the likelihood and
 3 severity of withdrawal associated with chronic opioid therapy. Janssen
 4 also knew or should have known that the patients involved in the study
 5 were not on the drug long enough to develop rates of withdrawal
 6 symptoms comparable to rates of withdrawal suffered by patients who
 7 use opioids for chronic pain—the use for which Janssen promoted
 8 Nucynta ER.

- 9 ○ Janssen sales representatives told prescribers that patients on Janssen’s
 10 drugs were less susceptible to withdrawal than those on other opioids.
- 11 ● Cephalon:
 - 12 ○ Cephalon sponsored FSMB’s Responsible Opioid Prescribing (2007),
 13 which taught that behaviors such as “requesting drugs by name,”
 14 “demanding or manipulative behavior,” seeing more than one doctor
 15 to obtain opioids, and hoarding are all signs of pseudoaddiction.
 16 Cephalon also spent \$150,000 to purchase copies of the book in bulk
 17 and distributed it through its pain sales force to 10,000 prescribers and
 18 5,000 pharmacists.
- 19 ● Endo:
 - 20 ○ Endo distributed copies of a book by KOL Dr. Lynn Webster entitled
 21 *Avoiding Opioid Abuse While Managing Pain* (2007). Endo’s internal
 22 planning documents describe the purpose of distributing this book as
 23 to “[i]ncrease the breadth and depth of the Opana ER prescriber base.”
 24 The book claims that when faced with signs of aberrant behavior, the
 25 doctor should regard it as pseudoaddiction and thus, increasing the
 26 dose in most cases . . . should be the clinician’s first response.”
 27
 28

- Endo spent \$246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."
- A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.
- Endo misrepresented that "symptoms of withdrawal do not indicate addiction."³⁴⁹
- "Endo also trained its sales representatives to distinguish addiction from 'pseudoaddiction.'"³⁵⁰

533. The RICO Defendants misrepresented that opioids were safe for the long-term treatment of chronic, non-acute, and non-cancer pain:

- Purdue:

- "[W]e do not want to niche OxyContin just for cancer pain."³⁵¹

three tablet strengths were passed around. OxyContin will be indicated for the relief of pain with the convenience of q12h dosing. OxyContin's primary market positioning will be for cancer pain and the secondary market will be for non-malignant pain (musculoskeletal, injury and trauma). It was reinforced that we do not want to niche OxyContin just for cancer pain. OxyContin will be positioned into Step 2 of the

- OxyContin was safe and non-addictive when using extended release formulations, and appropriate for use in non-cancer patients.³⁵²

³⁴⁹ *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15, at 7 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

³⁵⁰ *Id.*

³⁵¹ Ryan, *Description of Hell*, <http://documents.latimes.com/oxycontin-launch-1995/> (emphasis in the L.A. Times document).

³⁵² Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), http://www.opb.org/news/article/america_pain_foundation_shuts_down_as_senato

○ OxyContin should be prescribed not merely for severe short-term pain associated with surgery or cancer, but also for less acute, longer-lasting pain like arthritis, back pain, sports injuries, fibromyalgia with almost limitless treatment potential.³⁵³

• Janssen:

- Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence.”³⁵⁴
- Duragesic was “not just for end stage cancer anymore” when the FDA only approved Duragesic for “the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means.”³⁵⁵
- Misrepresented that “Duragesic can be used for any type of pain management” despite the fact that the FDA approved warning stated that “BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED: In the management of acute or post-operative pain, including use in outpatient surgeries”³⁵⁶
- Misrepresented “numerous claims for the efficacy and safety of Duragesic,” but failed to “present[] any risk information concerning the boxed warnings, contraindications, warnings, or side effects

rs_launch_investigation_of_prescription_narcotis/ (hereinafter “Ornstein, *American Pain Foundation*”).

³⁵³ Patrick Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>

³⁵⁴ NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

³⁵⁵ *Id.*

³⁵⁶ *Id.*

1 associated with Duragesic's use . . . [and] . . . fail[ed] to address
 2 important risks and restrictions associated with Duragesic therapy.”³⁵⁷

- 3 ○ Misrepresented “[d]emonstrated effectiveness in chronic back pain
 4 with additional patient benefits, . . . 86% of patients experienced
 5 overall benefit in a clinical study based on: pain control, disability in
 6 ADLs, quality of sleep.”³⁵⁸

7 • Cephalon:

- 8 ○ “[P]romoting [Actiq] for non-cancer patients to use for such maladies
 9 as migraines, sickle-cell pain crises, injuries, and in anticipation of
 10 changing wound dressings or radiation therapy.”³⁵⁹
 11 ○ “[P]romot[ing] Actiq for use in patients who were not yet opioid
 12 tolerant, and for whom it could have life-threatening results.”³⁶⁰
 13 ○ In 2011, Cephalon wrote an article titled “2011 Special Report: An
 14 Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl
 15 Buccal Tablet (FENTORA®) AND Oral Transmucosal Fentanyl
 16 Citrate (Actiq®), published in Pain Medicine News. Plaintiffs are
 17 informed and believe that Cephalon misrepresented that its drugs were
 18 “shown to be effective in treatment of [break through pain] associated
 19 with multiple causes of pain,” not just cancer.

20 534. The RICO Defendants also misrepresented that opioids were safer than
 21 non-opioid analgesics because there is no ceiling dose for opioid treatment.

22 • Purdue:

23
 24
 25 ³⁵⁷ *Id.*

26 ³⁵⁸ *Id.* at 2-3.

27 ³⁵⁹ Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon
 To Pay \$425 Million For Off-Label Drug Marketing (Sept. 29, 2008),
<https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf>.

28 ³⁶⁰ *Id.*

- Purdue's In the Face of Pain website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what—in their view—is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands.
- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones, which suggested that high dose opioids are safe and appropriate and did not disclose the risks from high dose opioids. This publication is still available online.
- Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses.
- *Treatment Options*, also taught that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. *Treatment Options* continued, warning that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose.
- Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and

1 taught that other drugs, but not opioids, are unsafe at high doses. The
2 2013 version is still available for CME credit.

- 3 ○ *Overview of Management Options* also taught NSAIDs and other
4 drugs, but not opioids, are unsafe at high doses.
- 5 ○ Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings
6 of the risk of interactions between opioids and benzodiazepines, which
7 would increase fatality risk. *Exit Wounds* also contained a lengthy
8 discussion of the dangers of using alcohol to treat chronic pain but did
9 not disclose dangers of mixing
- 10 ○ Purdue sales representatives told prescribers that opioids were just as
11 effective for treating patients long-term and omitted any discussion
12 that increased tolerance would require increasing, and increasingly
13 dangerous, doses.
- 14 ○ Purdue sales representatives told prescribers that NSAIDs were more
15 toxic than opioids.

- 16 • Janssen:

- 17 ○ Janssen sponsored a patient education guide entitled *Finding Relief:*
18 *Pain Management for Older Adults* (2009), which its personnel
19 reviewed and approved and its sales force distributed. This guide listed
20 dose limitations as “disadvantages” of other pain medicines but
21 omitted any discussion of risks of increased doses from opioids. The
22 publication also falsely claimed that it is a “myth” that “opioid doses
23 have to be bigger over time.”
- 24 ○ *Finding Relief: Pain Management for Older Adults* also described the
25 advantages and disadvantages of NSAIDs on one page, and the
26 “myths/facts” of opioids on the facing page. The disadvantages of
27 NSAIDs are described as involving “stomach upset or bleeding,”
28

1 “kidney or liver damage if taken at high doses or for a long time,”
 2 “adverse reactions in people with asthma,” and “can increase the risk
 3 of heart attack and stroke.” The only adverse effects of opioids listed
 4 are “upset stomach or sleepiness,” which the brochure claims will go
 5 away, and constipation.

- 6 ○ Janssen sponsored APF’s *Exit Wounds* (2009), which omits warnings
 7 of the risk of interactions between opioids and benzodiazepines.
 8 Janssen’s label for Duragesic, however, states that use with
 9 benzodiazepines “may cause respiratory depression, [low blood
 10 pressure], and profound sedation or potentially result in coma. Exit
 11 Wounds also contained a lengthy discussion of the dangers of using
 12 alcohol to treat chronic pain but did not disclose dangers of mixing
 13 alcohol and opioids.
- 14 ○ Janssen sales representatives told prescribers that Nucynta was not an
 15 opioid, making it a good choice for chronic pain patients who
 16 previously were unable to continue opioid therapy due to excessive
 17 side effects. This statement was misleading because Nucynta is an
 18 opioid and has the same effects as other opioids.
- 19 • Cephalon:
 - 20 ○ Cephalon sponsored APF’s *Treatment Options: A Guide for People*
 21 *Living with Pain* (2007), which claims that some patients “need” a
 22 larger dose of their opioid, regardless of the dose currently prescribed.
 - 23 ○ *Treatment Options*, also taught patients that opioids differ from
 24 NSAIDs in that they have “no ceiling dose” and are therefore the most
 25 appropriate treatment for severe pain. *Treatment Options* continued,
 26 warning that risks of NSAIDs increase if “taken more than a period of
 27 months.” With no corresponding warning about opioids. The
 28

publication attributed 10,000 to 20,000 deaths annually to NSAID overdose.

- Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations.
- Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.
- Cephalon sales representatives told prescribers that NSAIDs were more toxic than opioids.
- “[P]romot[ing] Actiq for use in patients who were not yet opioid tolerant, and for whom it could have life-threatening results.”³⁶¹
- Endo:
 - Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that opioids may be increased until “you are on the right dose of medication for your pain,” and once that occurs, further dose increases would not occur. Endo funded the site, which was a part of Endo’s marketing plan, and tracked visitors to it.
 - Through painknowledge.com Endo distributed a flyer called “Pain: Opioid Therapy.” This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.

³⁶¹ *Id.*

- 1 ○ Endo provided grants to APF to distribute Exit Wounds (2009), which
- 2 omitted warnings of the risk of interactions between opioids and
- 3 benzodiazepines, which would increase fatality risk. Exit Wounds also
- 4 contained a lengthy discussion of the dangers of using alcohol to treat
- 5 chronic pain but did not disclose dangers of mixing alcohol and
- 6 opioids.
- 7 ○ Endo sales representatives told prescribers that NSAIDs were more
- 8 toxic than opioids.
- 9 ○ Endo distributed a patient education pamphlet edited by KOL Dr.
- 10 Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid*
- 11 *Analgesics*. In Q&A format, it asked: “If I take the opioid now, will it
- 12 work later when I really need it?” The response was: “The dose can be
- 13 increased You won’t ‘run out’ of pain relief.”
- 14 ○ Endo distributed a “case study” to prescribers *titled Case Challenges*
- 15 *in Pain Management: Opioid Therapy for Chronic Pain*. The study
- 16 cites an example, meant to be representative, of a patient “with a
- 17 massive upper gastrointestinal bleed believed to be related to his
- 18 protracted use of NSAIDs” (over eight years), and recommends
- 19 treating with opioids instead.

20 535. These misrepresentations, and the legion of other representations made
 21 by the RICO Defendants and members of Opioid Marketing Enterprise all furthered
 22 the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.
 23 But they were demonstrably false, as confirmed by investigations and enforcement
 24 actions against the RICO Marketing Defendants.

25 536. In May 2007, Purdue and three of its executives pled guilty to federal
 26 charges of misbranding OxyContin in what the company acknowledged was an
 27 attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay
 28 \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of

OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. The Order adopting the guilty pleas provide:

effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

- d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
- e. Told certain health care providers that OxyContin did not cause a “buzz” or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to “weed out” addicts and drug seekers.

(Information ¶ 19.) Purdue has agreed that these facts are true, and the individual defendants, while they do not agree that they had knowledge of these things, have agreed that the court may accept these facts in support of their guilty pleas. (Agreed Statement of Facts ¶ 46.)

537. Additionally, Michael Friedman (“Friedman”), the company’s president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell (“Udell”), Purdue’s top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim (“Goldenheim”), its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.³⁶²

538. In a statement announcing the guilty plea, John Brownlee (“Brownlee”), the U.S. Attorney for the Western District of Virginia, stated:

Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. Purdue’s marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.

But OxyContin offered no miracles to those suffering in pain. Purdue’s claims that OxyContin was less addictive and less subject to abuse and

³⁶² *Id.*

diversion were false – and Purdue knew its claims were false. The result of their misrepresentations and crimes sparked one of our nation’s greatest prescription drug failures. . . . OxyContin was the child of marketers and bottom line financial decision making.³⁶³

539. Brownlee characterized Purdue’s criminal activity as follows:

First, Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

Second, Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction than immediate-release opioids.

Third, Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer “peak and trough” blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.

Fourth, Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug.

And fifth, Purdue falsely told health care providers that OxyContin did not cause a “buzz” or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to “weed out” addicts and drug seekers.³⁶⁴

540. Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Friedman, Udell and Goldenheim pled guilty to the misdemeanor charge of misbranding OxyContin for introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(1)-(2) and 352(a).

541. Similarly, Endo’s marketing of Purdue was criticized and punished by the FDA and New York Attorney General.

³⁶³ Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), <https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf>.

³⁶⁴ *Id.*

542. On February 18, 2017, the State of New York announced a settlement with Endo requiring it “to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER.”³⁶⁵ In the Assurance of Discontinuance that effectuated the settlement, the State of New York stated that Endo knew about the risks arising from the reformulated Opana ER even before it received FDA approval. Among other things, the investigation concluded that:

- Endo improperly marketed Opana ER as designed to be crush resistant, when Endo’s own studies dating from 2009 and 2010 showed that the pill could be crushed and ground;
- Endo improperly instructed its sales representatives to diminish and distort the risks associated with Opana ER, including the serious danger of addiction; and
- Endo made unsupported claims comparing Opana ER to other opioids and failed to disclose accurate information regarding studies addressing the negative effects of Opana ER.³⁶⁶

543. The 2017 settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that “[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant.” The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.³⁶⁷

³⁶⁵ Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016), <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals> (last accessed on March 9, 2018).

³⁶⁶ *Id.*

³⁶⁷ *Id.* at 6.

1 544. The Office of the Attorney General of New York also revealed that the
 2 “managed care dossier” Endo provided to formulary committees of healthcare plans
 3 and pharmacy benefit managers misrepresented the studies that had been conducted
 4 on Opana ER. According to Endo’s vice president for pharmacovigilance and risk
 5 management, the dossier was presented as a complete compendium of all research
 6 on the drug. However, it omitted certain studies: Study 108 (completed in 2009)
 7 and Study 109 (completed in 2010), which showed that reformulated Opana ER
 8 could be ground and chewed.

9 545. The settlement also detailed Endo’s false and misleading
 10 representations about the non-addictiveness of opioids and Opana. For example,
 11 until April 2012, Endo’s website for the drug, www.opana.com, contained the
 12 following representation: ““Most healthcare providers who treat patients with pain
 13 agree that patients treated with prolonged opioid medicines usually do not become
 14 addicted.””³⁶⁸ However, Endo neither conducted nor possessed a survey
 15 demonstrating that most healthcare providers who treat patients with pain agree
 16 with that representation.

17 546. The Office of the Attorney General of New York also disclosed the
 18 following facts that it determined to violate Opana’s obligations to truthfully market
 19 its products:

20 a. Training materials provided by Endo to sales
 21 representatives stated: ““Symptoms of withdrawal do not
 22 indicate addiction.””³⁶⁹ This representation is inconsistent with
 23 the diagnosis of opioid-use disorder as provided in the
 24 Diagnostic and Statistical Manual of Mental Disorders by the
 25 American Psychiatric Association (Fifth Edition).
 26

27 _____
 28 ³⁶⁸ *Id.*

³⁶⁹ *Id.* at 7.

1 b. Endo trained its sales representatives to falsely
 2 distinguish addiction from “pseudoaddiction,” which it defined
 3 as a condition in which patients exhibit drug-seeking behavior
 4 that resembles but is not the same as addiction. Endo’s vice
 5 president for pharmacovigilance and risk management testified
 6 that he was not aware of any research validating the concept of
 7 pseudoaddiction.

8 547. On June 9, 2017, the FDA asked Endo to voluntarily cease sales of
 9 Opana ER after determining that the risks associated with its abuse outweighed the
 10 benefits. According to Dr. Janet Woodcock, director of the FDA’s Center for Drug
 11 Evaluation and Research, the risks include “several serious problems,” including
 12 “outbreaks of HIV and Hepatitis C from sharing the drug after it was extracted by
 13 abusers” and “a serious disease outbreak.”³⁷⁰ If Endo did not comply, the FDA
 14 stated that it “intends to take steps to formally require its removal by withdrawing
 15 approval.”³⁷¹

16 548. Like Purdue and Endo, Janssen was the subject of an FDA
 17 enforcement action that identified its marketing statements as misrepresentations.
 18 For example:

19 549. On February 15, 2000, the FDA sent Janssen a letter concerning the
 20 alleged dissemination of “homemade” promotional pieces that promoted Duragesic
 21 in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter,
 22 dated March 30, 2000, the FDA explained that the “homemade” promotional pieces
 23 were “false or misleading because they contain misrepresentations of safety
 24
 25
 26

27 ³⁷⁰ *FDA requests removal of Opana ER for risks related to abuse*, June 8, 2017,
[https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.ht](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm)
 28 m.

³⁷¹ *Id.*

1 information, broaden Duragesic's indication, contain unsubstantiated claims, and
2 lack fair balance.”³⁷²

3 550. The March 30, 2000 letter identified specific violations, including
4 misrepresentations that Duragesic had a low potential for abuse:

5 You present the claim, “Low abuse potential!” This claim suggests that
6 Duragesic has less potential for abuse than other currently available
7 opioids. However, this claim has not been demonstrated by substantial
8 evidence. Furthermore, this claim is contradictory to information in the
approved product labeling (PI) that states, “Fentanyl is a Schedule II
controlled substance and can produce drug dependence similar to that
produced by morphine.” Therefore, this claim is false or misleading.³⁷³

9 551. The March 30, 2000 letter also stated that the promotional materials
10 represented that Duragesic was “more useful in a broader range of conditions or
11 patients than has been demonstrated by substantial evidence.”³⁷⁴ Specifically, the
12 FDA stated that Janssen was marketing Duragesic for indications other than the
13 treatment of chronic pain that cannot otherwise be managed, for which it was
14 approved:

15 You present the claim, “It’s not just for end stage cancer anymore!”
16 This claim suggests that Duragesic can be used for any type of pain
management. However, the PI for Duragesic states, “Duragesic
17 (fentanyl transdermal system) is indicated in the management of
chronic pain in patients who require continuous opioid analgesia for
18 pain that cannot be managed by lesser means” Therefore, the
suggestion that Duragesic can be used for any type of pain management
19 promotes Duragesic[] for a much broader use than is recommended in
the PI, and thus, is misleading. In addition, the suggestion that
20 Duragesic can be used to treat any kind of pain is contradictory to the
boxed warning in the PI. Specifically, the PI states,

21 **BECAUSE SERIOUS OR LIFE-THREATENING**
22 **HYPOVENTILATION COULD OCCUR, DURAGESIC®**
23 **(FENTANYL TRANSDERMAL SYSTEM) IS**
CONTRAINDICATED:

26 ³⁷² NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to
27 Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.

28 ³⁷³ *Id.*

³⁷⁴ *Id.*

1 In the management of acute or post-operative pain, including use in
outpatient surgeries³⁷⁵

2 552. The March 30, 2000 letter also stated Janssen failed to adequately
3 present “contraindications, warnings, precautions, and side effects with a
4 prominence and readability reasonably comparable to the presentation of
5 information relating to the effectiveness of the product.”³⁷⁶

6 553. On February 15, 2000, the FDA sent Janssen a letter concerning the
7 alleged dissemination of “homemade” promotional pieces that promoted Duragesic
8 in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter,
9 dated March 30, 2000, the FDA explained that the “homemade” promotional pieces
10 were “false or misleading because they contain misrepresentations of safety
11 information, broaden Duragesic’s indication, contain unsubstantiated claims, and
12 lack fair balance.”³⁷⁷

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22 FDA stated that Janssen was marketing Duragesic for indications other than the
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24
25 ³⁷⁵ *Id.* at 2-3.

26 ³⁷⁶ *Id.* at 3 (emphasis in original).

27 ³⁷⁷ NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to
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28 ³⁷⁸ *Id.*

³⁷⁹ *Id.*

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9 suggestion that Duragesic can be used for any type of pain management
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11 the PI, and thus, is misleading. In addition, the suggestion that
12 Duragesic can be used to treat any kind of pain is contradictory to the
13 boxed warning in the PI. Specifically, the PI states,

14 **BECAUSE SERIOUS OR LIFE-THREATENING**
15 **HYPOVENTILATION COULD OCCUR, DURAGESIC®**
16 **(FENTANYL TRANSDERMAL SYSTEM) IS**
17 **CONTRAINDICATED:**

18 In the management of acute or post-operative pain, including use in
19 outpatient surgeries³⁸⁰

20 556. The March 30, 2000 letter also stated Janssen failed to adequately
21 present “contraindications, warnings, precautions, and side effects with a
22 prominence and readability reasonably comparable to the presentation of
23 information relating to the effectiveness of the product”:

24 Although this piece contains numerous claims for the efficacy and
25 safety of Duragesic, you have not presented any risk information
26 concerning the boxed warnings, contraindications, warnings,
27 precautions, or side effects associated with Duragesic’s use
28 Therefore, this promotional piece is lacking in fair balance, or
otherwise misleading, because it fails to address important risks and
restrictions associated with Duragesic therapy.³⁸¹

557. On September 2, 2004, the U.S. Department of Health and Human
Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to “false
or misleading claims about the abuse potential and other risks of the drug, and . . .
unsubstantiated effectiveness claims for Duragesic,” including, specifically,

³⁸⁰ *Id.* at 2-3.

³⁸¹ *Id.* at 3 (emphasis in original).

1 “suggesting that Duragesic has a lower potential for abuse compared to other opioid
2 products.”

3 558. The September 2, 2004 letter warned Janssen regarding its claims that
4 Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network
5 (“DAWN”) as compared to other opioids. The letter stated that the claim was false
6 or misleading because the claim was not based on substantial data and because the
7 lower rate of mentions was likely attributable to Duragesic’s lower frequency of use
8 compared to other opioids listed in DAWN:

9 The file card presents the prominent claim, “Low reported rate
10 of mentions in DAWN data,” along with Drug Abuse Warning Network
11 (DAWN) data comparing the number of mentions for
12 Fentanyl/combinations (710 mentions) to other listed opioid products,
13 including Hydrocodone/combinations (21,567 mentions),
Oxycodone/combinations (18,409 mentions), and Methadone (10,725
mentions). The file card thus suggests that Duragesic is less abused
than other opioid drugs.

14 This is false or misleading for two reasons. First, we are not
15 aware of substantial evidence or substantial clinical experience to
16 support this comparative claim. The DAWN data cannot provide the
17 basis for a valid comparison among these products. As you know,
DAWN is not a clinical trial database. Instead, it is a national public
health surveillance system that monitors drug-related emergency
department visits and deaths. If you have other data demonstrating that
Duragesic is less abused, please submit them.

18 Second, Duragesic is not as widely prescribed as other opioid
19 products. As a result, the relatively lower number of mentions could be
20 attributed to the lower frequency of use, and not to a lower incidence of
abuse. The file card fails to disclose this information.³⁸²

21 559. The September 2, 2004 letter also detailed a series of unsubstantiated
22 false or misleading claims regarding Duragesic’s effectiveness. The letter
23 concluded that various claims made by Janssen were insufficiently supported,
24 including:

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26
27 ³⁸² Warning Letter from Thomas W. Abrams, U.S. Department of Health and
Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc. (Sept. 2, 2004),
28 https://www.pharmamedtechbi.com/~media/Images/Publications/Archive/The%20Pink%20Sheet/66/038/00660380018/040920_duragesic_letter.pdf at 2.

- 1 • “‘Demonstrated effectiveness in chronic back pain with additional patient
- 2 benefits, . . . 86% of patients experienced overall benefit in a clinical study
- 3 based on: pain control, disability in ADLs, quality of sleep.’”
- 4 • “‘All patients who experienced overall benefit from DURAGESIC would
- 5 recommend it to others with chronic low back pain.’”
- 6 • “‘Significantly reduced nighttime awakenings.’”
- 7 • “‘Significant improvement in disability scores as measured by the Oswestry
- 8 Disability Questionnaire and Pain Disability Index.’”
- 9 • “‘Significant improvement in physical functioning summary score.’”
- 10 • “‘Significant improvement in social functioning.’”³⁸³

11 560. In addition, the September 2, 2004 letter identified “outcome claims

12 [that] are misleading because they imply that patients will experience improved

13 social or physical functioning or improved work productivity when using

14 Duragesic.” The claims include “‘1,360 loaves . . . and counting,’ ‘[w]ork,

15 uninterrupted,’ ‘[l]ife, uninterrupted,’ ‘[g]ame, uninterrupted,’ ‘[c]hronic pain relief

16 that supports functionality,’ ‘[h]elps patients think less about their pain,’ and

17 ‘[i]mprove[s] . . . physical and social functioning.’” The September 2, 2004 letter

18 stated: “Janssen has not provided references to support these outcome claims. We

19 are not aware of substantial evidence or substantial clinical experience to support

20 these claims.”³⁸⁴

21 561. On July 15, 2005, the FDA issued a public health advisory warning

22 doctors of deaths resulting from the use of Duragesic and its generic competitor,

23 manufactured by Mylan N.V. Plaintiffs are informed and believe that the advisory

24 noted that the FDA had been “‘examining the circumstances of product use to

25 determine if the reported adverse events may be related to inappropriate use of the

27 ³⁸³ *Id.* at 2-3.

28 ³⁸⁴ *Id.* at 3.

1 patch” and noted the possibility “that patients and physicians might be unaware of
 2 the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic
 3 meant to treat chronic pain that does not respond to other painkillers.³⁸⁵

4 562. Finally, Cephalon has been the subject of investigations and
 5 enforcement actions for is misrepresentations concerning Actiq. For example:

6 563. In October 2000, Cephalon acquired the worldwide product rights to
 7 Actiq and began marketing and selling Actiq in the United States. The FDA
 8 explicitly stated that Actiq “*must not* be used in opioid non-tolerant patients,” was
 9 contraindicated for the management of acute or postoperative pain, could be deadly
 10 to children, and was “intended to be used only in the care of opioid-tolerant cancer
 11 patients and only by oncologists and pain specialists who are knowledgeable of and
 12 skilled in the use of Schedule II opioids to treat cancer pain.”³⁸⁶ The FDA also
 13 required that Actiq be provided only in compliance with a strict risk management
 14 program that explicitly limited the drug’s direct marketing to the approved target
 15 audiences, defined as oncologists, pain specialists, their nurses and office staff.³⁸⁷

16 564. Cephalon purchased the rights to Fentora, an even faster-acting tablet
 17 formulation of fentanyl, from Cima Labs, and submitted a new drug application to
 18 the FDA in August 2005. In September 2006, Cephalon received FDA approval to
 19 sell this faster-acting version of Actiq; but once again, concerned about the power
 20 and risks inherent to fentanyl, the FDA limited Fentora’s approval to the treatment
 21 of BTP in cancer patients who were already tolerant to around-the-clock opioid
 22 therapy for their underlying persistent cancer pain. Cephalon began marketing and
 23 selling Fentora in October 2006.

24
 25 ³⁸⁵ *New Fentanyl Warnings: More Needed to Protect Patients*, Institute for Safe
 26 Medication Practices, August 11, 2005,
<https://www.ismp.org/newsletters/acute care/articles/20050811.asp>

27 ³⁸⁶ *Id.*

28 ³⁸⁷ See John Carreyrou, *Narcotic “Lollipop” Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), <https://www.opiates.com/media/narcotic-lollipop-becomes-big-seller-despite-fdacurbs/>.

1 565. Due to the FDA's restrictions, Actiq's consumer base was limited, as
 2 was its potential for growing revenue. In order to increase its revenue and market
 3 share, Cephalon needed to find a broader audience and thus began marketing its
 4 lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer
 5 pain, targeting non-oncology practices, including, but not limited to, pain doctors,
 6 general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so
 7 in violation of applicable regulations prohibiting the marketing of medications for
 8 off-label use and indirect contravention of the FDA's strict instructions that Actiq
 9 be prescribed only to terminal cancer patients and by oncologists and pain
 10 management doctors experienced in treating cancer pain.

11 566. Beginning in or about 2003, former Cephalon employees filed four
 12 whistleblower lawsuits claiming the company had wrongfully marketed Actiq for
 13 unapproved off-label uses. On September 29, 2008, Cephalon finalized and entered
 14 into a corporate integrity agreement with the Office of the Inspector General of
 15 HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label
 16 marketing of Actiq and two other drugs (Gabitril and Provigil).

17 According to a DOJ press release, Cephalon trained sales representatives to
 18 disregard restrictions of the FDA-approved label, employed sales representatives
 19 and healthcare professionals to speak to physicians about off-label uses of the three
 20 drugs and funded CME to promote off-label uses. Specifically, the DOJ stated:

21 From 2001 through at least 2006, Cephalon was allegedly promoting
 22 [Actiq] for non-cancer patients to use for such maladies as migraines,
 23 sickle-cell pain crises, injuries, and in anticipation of changing wound
 24 dressings or radiation therapy. Cephalon also promoted Actiq for use in
 patients who were not yet opioid-tolerant, and for whom it could have
 life-threatening results.³⁸⁸

25 567. Then-acting U.S. Attorney Laurie Magid commented on the dangers
 26 of Cephalon's unlawful practices:

27 ³⁸⁸ Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon
 28 To Pay \$425 Million For Off-Label Drug Marketing (Sept. 29, 2008),
<https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf>.

1 “This company subverted the very process put in place to protect the public
 2 from harm, and put patients’ health at risk for nothing more than boosting its
 3 bottom line. People have an absolute right to their doctors’ best medical
 4 judgment. They need to know the recommendations a doctor makes are not
 5 influenced by sales tactics designed to convince the doctor that the drug being
 6 prescribed is safe for uses beyond what the FDA has approved.”³⁸⁹

7 568. Upon information and belief, documents uncovered in the
 8 government’s investigations confirm that Cephalon directly targeted non-oncology
 9 practices and pushed its sales representatives to market Actiq for off-label use. For
 10 instance, the government’s investigations confirmed:

- 11 a. Cephalon instructed its sales representatives to ask non-cancer doctors
 12 whether they have the potential to treat cancer pain. Even if the doctor
 13 answered “no,” a decision tree provided by Cephalon instructed the sales
 14 representatives to give these physicians free Actiq coupons;
- 15 b. Cephalon targeted neurologists in order to encourage them to prescribe
 16 Actiq to patients with migraine headaches;
- 17 c. Cephalon sales representatives utilized the assistance of outside pain
 18 management specialists when visiting non-cancer physicians to pitch
 19 Actiq. The pain management specialist would falsely inform the physician
 20 that Actiq does not cause patients to experience a “high” and carries a low
 21 risk of diversion toward recreational use;
- 22 d. Cephalon set sales quotas for its sales and marketing representatives that
 23 could not possibly have been met solely by promoting Actiq for its FDA-
 24 approved indication;

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28 ³⁸⁹ *Id.*

- 1 e. Cephalon promoted the use of higher doses of Actiq than patients required
2 by encouraging prescriptions of the drug to include larger-than-necessary
3 numbers of lozenges with unnecessarily high doses of fentanyl; and
4 f. Cephalon promoted Actiq for off-label use by funding and controlling
5 CME seminars that promoted and misrepresented the efficacy of the drug
6 for off-label uses such as treating migraine headaches and for patients not
7 already opioid-tolerant.³⁹⁰

8 569. The FDA's letters and safety alerts, the DOJ and state investigations,
9 and the massive settlement seemed to have had little impact on Cephalon as it
10 continued its deceptive marketing strategy for both Actiq and Fentora.

11 570. On September 27, 2007, the FDA issued a public health advisory to
12 address numerous reports that patients who did not have cancer or were not opioid-
13 tolerant had been prescribed Fentora, and death or life-threatening side effects had
14 resulted. The FDA warned: "Fentora should not be used to treat any type of short-
15 term pain."³⁹¹

16 571. Nevertheless, in 2008, Cephalon pushed forward to expand the target
17 base for Fentora and filed a supplemental drug application requesting FDA approval
18 of Fentora for the treatment of non-cancer BTP. In the application and supporting
19 presentations to the FDA, Cephalon admitted both that it knew the drug was heavily
20 prescribed for off-label use and that the drug's safety for such use had never been
21 clinically evaluated.³⁹² An FDA advisory committee noted that Fentora's existing
22

23 ³⁹⁰ John Carreyrou, Cephalon Used Improper Tactics to Sell Drug, Probe Finds,
24 Wall St. J., Nov. 21, 2006, at B1 (hereinafter "Carreyrou, Cephalon Used Improper
Tactics").

25 ³⁹¹ Press Release, U.S. Food & Drug Administration, Public Health Advisory:
26 Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept.
27 26, 2007),
<https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

28 ³⁹² FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life
Support Drugs and

1 risk management program was ineffective and stated that Cephalon would have to
 2 institute a risk evaluation and mitigation strategy for the drug before the FDA would
 3 consider broader label indications. In response, Cephalon revised Fentora's label
 4 and medication guide to add strengthened warnings.

5 572. But in 2009, the FDA once again informed Cephalon that the risk
 6 management program was not sufficient to ensure the safe use of Fentora for already
 7 approved indications.

8 573. On March 26, 2009, the FDA warned Cephalon against its misleading
 9 advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora
 10 Internet advertisement as misleading because it purported to broaden "the indication
 11 for Fentora by implying that any patient with cancer who requires treatment for
 12 breakthrough pain is a candidate for Fentora . . . when this is not the case."³⁹³ Rather,
 13 Fentora was only indicated for those who were already opioid tolerant. It further
 14 criticized Cephalon's other direct Fentora advertisements because they did not
 15 disclose the risks associated with the drug.

16 574. Flagrantly disregarding the FDA's refusal to approve Fentora for non-
 17 cancer BTP and its warning against marketing the drug for the same, Cephalon
 18 continued to use the same sales tactics to push Fentora as it did with Actiq.

19 575. The misrepresentations disseminated by members of the Opioid
 20 Marketing Enterprise, and the RICO Marketing Defendants, caused The County
 21 and California consumers to pay for excessive opioid prescriptions, suffer injuries
 22 and losses, and to incur costs associated with the opioid epidemic caused by the
 23 Opioid Marketing Enterprise.

24
 25
 26 Drug Safety and Risk Management Advisory Committee, U.S. Food & Drug
 Administration (May 6, 2008), [https://www.fda.gov/ohrms/dockets/
 ac/08/slides/2008-4356s2-03-Cephalon.pdf](https://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-03-Cephalon.pdf).

27 ³⁹³ Letter from Michael Sauers, Regulatory Review Officer, Division of Drug
 28 Marketing, Advertising and Communications, to Carole S. Marchione, Senior
 Director and Group Leader, Regulatory Affairs (March 26, 2009)

1 576. The RICO Marketing Defendants alone could not have accomplished
2 the purpose of the Opioid Marketing Enterprise without the assistance of the Front
3 Groups and KOLs, who were perceived as “neutral” and more “scientific” than the
4 RICO Defendants themselves. Without these misrepresentations, the Opioid
5 Marketing Enterprise could not have achieved its common purpose.

6 577. The impact of the Opioid Marketing Enterprise’s scheme is still in
7 place – i.e., the opioids continue to be prescribed and used for chronic pain
8 throughout the State of California, and the epidemic continues to injure The County,
9 and consume the resources of The County’s and California’s health care and law
10 enforcement systems.

11 578. The foregoing evidences that the RICO Marketing Defendants, the
12 Front Groups, and the KOLs were each willing participants in the Opioid Marketing
13 Enterprise, had a common purpose and interest in the object of the scheme, and
14 functioned within a structure designed to effectuate the Enterprise’s purpose.

15 **B. CONDUCT OF THE OPIOID MARKETING ENTERPRISE.**

16 579. During time period described in this Complaint, from approximately
17 the late 1990s to the present, the RICO Marketing Defendants exerted control over
18 the Opioid Marketing Enterprise and participated in the operation or management
19 of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the
20 following ways:

- 21 a. Creating a body of deceptive, misleading and unsupported medical and
22 popular literature about opioids that (a) understated the risks and
23 overstated the benefits of long-term use; (b) appeared to be the result of
24 independent, objective research; and (c) was thus more likely to be relied
25 upon by physicians, patients, and payors;
- 26 b. Creating a body of deceptive, misleading and unsupported electronic and
27 print advertisements about opioids that (a) understated the risks and
28 overstated the benefits of long-term use; (b) appeared to be the result of

- 1 independent, objective research; and (c) was thus more likely to be relied
2 upon by physicians, patients, and payors;
- 3 c. Creating a body of deceptive, misleading and unsupported sales and
4 promotional training materials about opioids that (a) understated the risks
5 and overstated the benefits of long-term use; (b) appeared to be the result
6 of independent, objective research; and (c) was thus more likely to be
7 relied upon by physicians, patients, and payors;
- 8 d. Creating a body of deceptive, misleading and unsupported CMEs and
9 speaker presentations about opioids that (a) understated the risks and
10 overstated the benefits of long-term use; (b) appeared to be the result of
11 independent, objective research; and (c) was thus more likely to be relied
12 upon by physicians, patients, and payors;
- 13 e. Selecting, cultivating, promoting and paying KOLs based solely on their
14 willingness to communicate and distribute the RICO Defendants'
15 messages about the use of opioids for chronic pain;
- 16 f. Providing substantial opportunities for KOLs to participate in research
17 studies on topics the RICO Defendants suggested or chose, with the
18 predictable effect of ensuring that many favorable studies appeared in the
19 academic literature;
- 20 g. Paying KOLs to serve as consultants or on the RICO Defendants'
21 advisory boards, on the advisory boards and in leadership positions on
22 Front Groups, and to give talks or present CMEs, typically over meals or
23 at conferences;
- 24 h. Selecting, cultivating, promoting, creating and paying Front Groups based
25 solely on their willingness to communicate and distribute the RICO
26 Defendants' messages about the use of opioids for chronic pain;
- 27 i. Providing substantial opportunities for Front Groups to participate in
28 and/or publish research studies on topics the RICO Defendants suggested

- 1 or chose (and paid for), with the predictable effect of ensuring that many
2 favorable studies appeared in the academic literature;
- 3 j. Paying significant amounts of money to the leaders and individuals
4 associated with Front Groups;
- 5 k. Donating to Front Groups to support talks or CMEs, that were typically
6 presented over meals or at conferences;
- 7 l. Disseminating many of their false, misleading, imbalanced, and
8 unsupported statements through unbranded materials that appeared to be
9 independent publications from Front Groups;
- 10 m. Sponsoring CME programs put on by Front Groups that focused
11 exclusively on the use of opioids for chronic pain;
- 12 n. Developing and disseminating pro-opioid treatment guidelines with the
13 help of the KOLs as authors and promoters, and the help of the Front
14 Groups as publishers, and supporters;
- 15 o. Encouraging Front Groups to disseminate their pro-opioid messages to
16 groups targeted by the RICO Defendants, such as veterans and the elderly,
17 and then funded that distribution;
- 18 p. Concealing their relationship to and control of Front Groups and KOLs
19 from the The County and the public at large; and
- 20 q. Intending that Front Groups and KOLs would distribute through the U.S.
21 mail and interstate wire facilities, promotional and other materials that
22 claimed opioids could be safely used for chronic pain.

23
24 580. The Front Groups also participated in the conduct of the Opioid
25 Marketing Enterprise, directly or indirectly, in the following ways:

- 26 a. The Front Groups promised to, and did, make representations regarding
27 opioids and the RICO Marketing Defendants' drugs that were consistent
28 with the RICO Marketing Defendants' messages;

- b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

581. The RICO Marketing Defendants’ Front Groups, “with their large numbers and credibility with policymakers and the public—have ‘extensive influence in specific disease areas.’” The RICO Marketing Defendants’ larger Front Groups “likely have a substantial effect on policies relevant to their industry sponsors.”³⁹⁴ “By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic.”³⁹⁵

³⁹⁴ *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, February 12, 2018 <https://www.hsdl.org/?abstract&did=808171> (“*Fueling an Epidemic*”), at 1.

³⁹⁵ *Id.* 2.

1 582. The KOLs also participated, on information and belief, in the conduct
2 of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the
3 following ways:

- 4 a. The KOLs promised to, and did, make representations regarding opioids
5 and the RICO Marketing Defendants' drugs that were consistent with the
6 RICO Marketing Defendants' messages themselves;
- 7 b. The KOLs distributed, through the U.S. Mail and interstate wire facilities,
8 promotional and other materials which claimed that opioids could be
9 safely used for chronic pain without addiction, and misrepresented the
10 benefits of using opioids for chronic pain outweighed the risks;
- 11 c. The KOLs echoed and amplified messages favorable to increased opioid
12 use—and ultimately, the financial interests of the RICO Marketing
13 Defendants;
- 14 d. The KOLs issued guidelines and policies minimizing the risk of opioid
15 addiction and promoting opioids for chronic pain;
- 16 e. The KOLs strongly criticized the 2016 guidelines from the Center for
17 Disease Control and Prevention (CDC) that recommended limits on
18 opioid prescriptions for chronic pain; and
- 19 f. The KOLs concealed their connections to the Front Groups and the RICO
20 Defendants, and their sponsorship by the RICO Marketing Defendants.

21 583. The scheme devised and implemented by the RICO Marketing
22 Defendants and members of the Opioid Marketing Enterprise, amounted to a
23 common course of conduct intended to increase the RICO Marketing Defendants
24 sales from prescription opioids by encouraging the prescribing and use of opioids
25 for long-term chronic pain. The scheme was a continuing course of conduct, and
26 many aspects of it continue through to the present.
27
28

1 **C. PATTERN OF RACKETEERING ACTIVITY**

2 584. The RICO Marketing Defendants conducted and participated in the
3 conduct of the Opioid Marketing Enterprise through a pattern of racketeering
4 activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail
5 and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire
6 fraud).

7 585. The RICO Marketing Defendants committed, conspired to commit,
8 and/or aided and abetted in the commission of at least two predicate acts of
9 racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past
10 ten years. The multiple acts of racketeering activity that the RICO Marketing
11 Defendants committed, or aided and abetted in the commission of, were related to
12 each other, posed a threat of continued racketeering activity, and therefore
13 constitute a “pattern of racketeering activity.” The racketeering activity was made
14 possible by the RICO Marketing Defendants’ regular use of the facilities, services,
15 distribution channels, and employees of the Opioid Marketing Enterprise, the U.S.
16 Mail and interstate wire facilities. The RICO Marketing Defendants participated in
17 the scheme to defraud by using mail, telephones and the Internet to transmit
18 mailings and wires in interstate or foreign commerce.

19 586. The pattern of racketeering activity described herein used by the RICO
20 Marketing Defendants and the Opioid Marketing Enterprise likely involved
21 thousands of separate instances of the use of the U.S. Mail or interstate wire
22 facilities in furtherance of the unlawful Opioid Marketing Enterprise, including
23 virtually uniform misrepresentations, concealments and material omissions
24 regarding the beneficial uses and non-addictive qualities for the long-term treatment
25 of chronic, non-acute and non-cancer pain, with the goal of profiting from increased
26 sales of the RICO Marketing Defendants’ drugs induced by consumers, prescribers,
27 regulators and the County’s reliance on the RICO Marketing Defendants’
28 misrepresentations.

1 587. Each of these fraudulent mailings and interstate wire transmissions
2 constitutes racketeering activity and collectively, these violations constitute a
3 pattern of racketeering activity, through which Defendants, the Front Groups and
4 the KOLs defrauded and intended to defraud California consumers, the State, and
5 other intended victims.

6 588. In devising and executing the illegal scheme, the RICO Marketing
7 Defendants devised and knowingly carried out a material scheme and/or artifice to
8 defraud by means of materially false or fraudulent pretenses, representations,
9 promises, or omissions of material facts regarding the safe, non-addictive and
10 effective use of opioids for long-term chronic, non-acute and non-cancer pain. The
11 RICO Marketing Defendants and members of the Opioid Marketing Enterprise
12 knew that these representations violated the FDA approved use these drugs, and
13 were not supported by actual evidence. For the purpose of executing the illegal
14 scheme, the RICO Marketing Defendants intended that that their common purpose
15 and scheme to defraud would, and did, use the U.S. Mail and interstate wire
16 facilities, intentionally and knowingly with the specific intent to advance their
17 illegal scheme.

18 589. The RICO Marketing Defendants' predicate acts of racketeering (18
19 U.S.C. § 1961(1)) include, but are not limited to:

20 a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341
21 by sending or receiving, or by causing to be sent and/or received, materials
22 via U.S. mail or commercial interstate carriers for the purpose of
23 executing the unlawful scheme to design, manufacture, market, and sell
24 the prescription opioids by means of false pretenses, misrepresentations,
25 promises, and omissions.

26 b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343
27 by transmitting and/or receiving, or by causing to be transmitted and/or
28 received, materials by wire for the purpose of executing the unlawful

1 scheme to design, manufacture, market, and sell the prescription opioids
2 by means of false pretenses, misrepresentations, promises, and omissions.

3 590. Each instance of racketeering activity alleged herein was related, had
4 similar purposes, involved the same or similar participants and methods of
5 commission, and had similar results affecting similar victims, including California
6 consumers, prescribers, regulators and The County. The RICO Marketing
7 Defendants, Front Groups and KOLs calculated and intentionally crafted the
8 scheme and common purpose of the Opioid Marketing Enterprise to ensure their
9 own profits remained high. In designing and implementing the scheme, the RICO
10 Marketing Defendants understood and intended that those in the distribution chain
11 rely on the integrity of the pharmaceutical companies and ostensibly neutral third
12 parties to provide objective and scientific evidence regarding the RICO Marketing
13 Defendants' products.

14 591. By intentionally misrepresenting the risks and benefits of using opioids
15 for chronic pain, and then subsequently failing to disclose such practices to
16 California consumers, prescribers, regulators and The County. Defendants, the
17 Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct
18 constituting a pattern of racketeering activity.

19 592. The racketeering activities conducted by the RICO Marketing
20 Defendants, Front Groups and KOLs amounted to a common course of conduct,
21 with a similar pattern and purpose, intended to deceive California consumers,
22 prescribers, regulators and The County. Each separate use of the U.S. Mail and/or
23 interstate wire facilities employed by Defendants was related, had similar intended
24 purposes, involved similar participants and methods of execution, and had the same
25 results affecting the same victims, including California consumers, prescribers,
26 regulators and The County. The RICO Marketing Defendants have engaged in the
27 pattern of racketeering activity for the purpose of conducting the ongoing business
28 affairs of the Opioid Marketing Enterprise.

1 593. The RICO Marketing Defendants' pattern of racketeering activity
2 alleged herein and the Opioid Marketing Enterprise are separate and distinct from
3 each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid
4 Marketing Enterprise.

5 594. The pattern of racketeering activity alleged herein is continuing as of
6 the date of this complaint, and, upon information and belief, will continue into the
7 future unless enjoined by this Court.

8 595. Many of the precise dates of the Opioid Marketing Enterprise's uses
9 of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of
10 mail and wire fraud) have been hidden and cannot be alleged without access to the
11 books and records maintained by the RICO Marketing Defendants, Front Groups,
12 and KOLs. Indeed, an essential part of the successful operation of the Opioid
13 Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiffs
14 have described the occasions on which the RICO Marketing Defendants, Front
15 Groups, and KOLs disseminated misrepresentations and false statements to
16 California consumers, prescribers, regulators and The County, and how those acts
17 were in furtherance of the scheme, and do so further below.

18 596. The RICO Marketing Defendants' use of the U.S. Mail and interstate
19 wire facilities to perpetrate the opioids marketing scheme involved thousands of
20 communications, publications, representations, statements, electronic
21 transmissions, payments, including, *inter alia*:

- 22 a. Marketing materials about opioids, and their risks and benefits, which the
23 RICO Marketing Defendants sent to health care providers, transmitted
24 through the internet and television, published, and transmitted to Front
25 Groups and KOLs located across the country and the State;
26 b. Written representations and telephone calls between the RICO Marketing
27 Defendants and Front Groups regarding the misrepresentations,
28

- 1 marketing statements and claims about opioids, including the non-
2 addictive, safe use of chronic long-term pain generally;
- 3 c. Written representations and telephone calls between the RICO Marketing
4 Defendants and KOLs regarding the misrepresentations, marketing
5 statements and claims about opioids, including the non-addictive, safe use
6 of chronic long-term pain generally;
- 7 d. E-mails, telephone and written communications between the RICO
8 Marketing Defendants and the Front Groups agreeing to or implementing
9 the opioids marketing scheme;
- 10 e. E-mails, telephone and written communications between the RICO
11 Marketing Defendants and the KOLs agreeing to or implementing the
12 opioids marketing scheme;
- 13 f. Communications between the RICO Marketing Defendants, Front Groups
14 and the media regarding publication, drafting of treatment guidelines, and
15 the dissemination of the same as part of the Opioid Marketing Enterprise;
- 16 g. Communications between the RICO Marketing Defendants, KOLs and
17 the media regarding publication, drafting of treatment guidelines, and the
18 dissemination of the same as part of the Opioid Marketing Enterprise;
- 19 h. Written and oral communications directed to State agencies, federal and
20 state courts, and private insurers throughout the State that fraudulently
21 misrepresented the risks and benefits of using opioids for chronic pain;
22 and
- 23 i. Receipts of increased profits sent through the U.S. Mail and interstate wire
24 facilities – the wrongful proceeds of the scheme.

25 597. In addition to the above-referenced predicate acts, it was foreseeable
26 to the RICO Marketing Defendants that the Front Groups and the KOLs would
27 distribute publications through the U.S. Mail and by interstate wire facilities, and,
28 in those publications, claim that the benefits of using opioids for chronic pain

1 outweighed the risks of doing so.

2 598. The RICO Marketing Defendants aided and abetted others in the
3 violations of the above laws, thereby rendering them indictable as principals in the
4 18 U.S.C. §§ 1341 and 1343 offenses.

5 599. To achieve the common goal and purpose of the Opioid Marketing
6 Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing
7 Enterprise hid from the consumers, prescribers, regulators and The County: (1) the
8 fraudulent nature of the RICO Marketing Defendants' marketing scheme; (2) the
9 fraudulent nature of statements made by the RICO Marketing Defendants and by
10 their KOLs, Front Groups and other third parties regarding the safety and efficacy
11 of prescription opioids; and (3) the true nature of the relationship between the
12 members of the Opioid Marketing Enterprise.

13 600. The RICO Marketing Defendants, and each member of the Opioid
14 Marketing Enterprise agreed, with knowledge and intent, to the overall objective of
15 the RICO Marketing Defendants' fraudulent scheme and participated in the
16 common course of conduct to commit acts of fraud and indecency in marketing
17 prescription opioids.

18 601. Indeed, for the RICO Marketing Defendants' fraudulent scheme to
19 work, each of the RICO Marketing Defendants had to agree to implement similar
20 tactics regarding fraudulent marketing of prescription opioids. This conclusion is
21 supported by the fact that the RICO Marketing Defendants each financed,
22 supported, and worked through the same KOLs and Front Groups, and often
23 collaborated on and mutually supported the same publications, CMEs,
24 presentations, and prescription guidelines.

25 602. As described herein, the RICO Marketing Defendants engaged in a
26 pattern of related and continuous predicate acts for years. The predicate acts
27 constituted a variety of unlawful activities, each conducted with the common
28 purpose of obtaining significant money and revenue from the marketing and sale of

1 their highly addictive and dangerous drugs. The predicate acts also had the same or
2 similar results, participants, victims, and methods of commission. The predicate
3 acts were related and not isolated events.

4 603. The RICO Marketing Defendants predicate acts all had the purpose of
5 creating the opioid epidemic that substantially injured The County's business and
6 property, while simultaneously generating billion-dollar revenue and profits for the
7 RICO Marketing Defendants. The predicate acts were committed or caused to be
8 committed by the RICO Marketing Defendants through their participation in the
9 Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

10 604. The RICO Marketing Defendants' predicate acts and pattern of
11 racketeering activity were a substantial and foreseeable cause of The County's
12 injury and the relationship between the RICO Marketing Defendants' conduct and
13 The County's injury is logical and not speculative. It was foreseeable to the RICO
14 Marketing Defendants that when they fraudulently marketed highly-addictive and
15 dangerous drugs, that were approved for very limited and specific uses by the FDA,
16 as non-addictive and safe for off-label uses such as moderate pain, non-cancer pain,
17 and long-term chronic pain, that the RICO Marketing Defendants would create an
18 opioid-addiction epidemic that logically, substantially and foreseeably harmed The
19 County.

20 605. The pattern of racketeering activity alleged herein is continuing as of
21 the date of this Complaint and, upon information and belief, will continue into the
22 future unless enjoined by this Court. The last racketeering incident occurred within
23 five years of the commission of a prior incident of racketeering.

24 **D. DAMAGES.**

25 **1. Impact of the Opioid Marketing Enterprise.**

26 606. California has been especially ravaged by the national opioid crisis.

27 607. More people die each year from drug overdoses in California than in
28

any other state.³⁹⁶ The State's death rate has continued to climb, increasing by 30 percent from 1999 to 2015, according to the Center for Disease Control (CDC).³⁹⁷

608. In 2016, 1,925 Californians died due to prescription opioids.³⁹⁸ This number is on par with other recent years: in 2015, 1,966 deaths in California were due just to prescription opioids (not including heroin); in 2014 that number was even higher at 2,024 prescription opioid deaths; and in 2013, 1,934 Californians died from a prescription opioid overdose.³⁹⁹

609. Of the 1,925 opioid-related deaths in California in 2016, fentanyl was a factor in at least 234 of them.⁴⁰⁰ This is an increase of 47 percent for 2016.⁴⁰¹ Heroin-related deaths have risen by 67 percent in California since 2006.⁴⁰²

610. The high number of deaths is due in part to the extraordinary number of opioids prescribed in the State. Over 23.6 million prescriptions for opioids were written in California in just 2016.⁴⁰³

611. The California Department of Public Health tracks the number of reported hospitalizations and emergency department visits due to prescription opioids.⁴⁰⁴ In 2015, the last year for which information is currently available, California had 3,935 emergency department visits and 4,095 hospitalizations

³⁹⁶ Davis, *supra*.

³⁹⁷ Karlamangla, *supra*.

³⁹⁸ Davis, *supra*.

³⁹⁹ California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, *supra*.

⁴⁰⁰ Davis, *supra*.

⁴⁰¹ Karlamangla, *supra*.

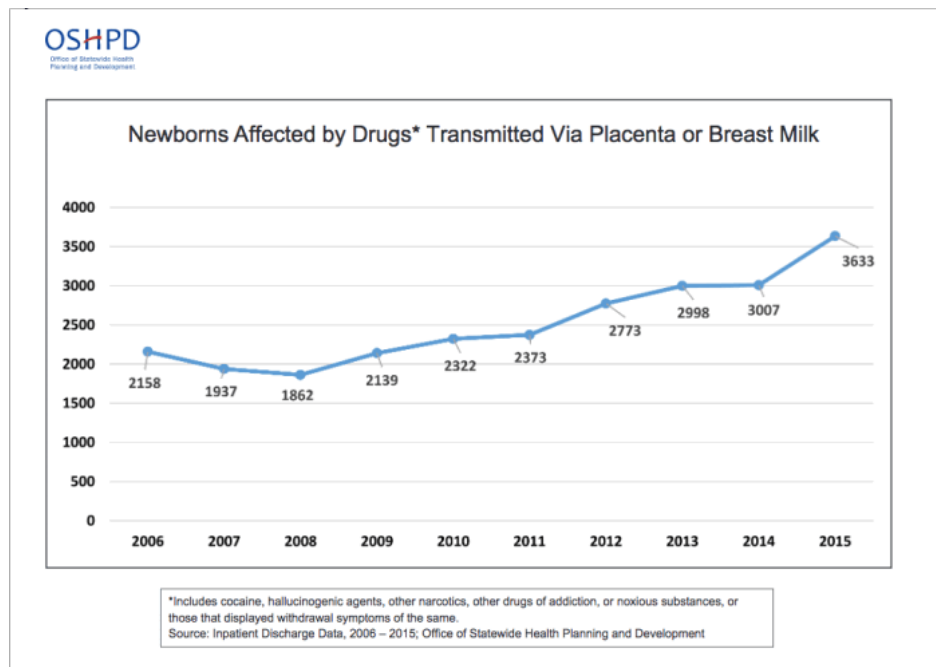
⁴⁰² California Department of Public Health, *State of California Strategies to Address Prescription Drug (Opioid) Misuse, Abuse, and Overdose Epidemic in California* at 3 (June 2016), available at <https://www.cdph.ca.gov/Programs/CCDCPHP/DCDIC/SACB/CDPH%20Documents/Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf> (last visited March 2, 2018).

⁴⁰³ California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, *supra*.

⁴⁰⁴ *Id.*

related to prescription opioid overdoses (excluding heroin).⁴⁰⁵ The numbers were even higher in 2014, when 4,106 people visited the emergency department and 4,482 people were hospitalized due to prescription opioid abuse.⁴⁰⁶ In 2013, there were 3,964 emergency department visits and 4,344 hospitalizations for prescription opioid overdoses.⁴⁰⁷ When emergency visits and hospitalizations include heroin, the numbers are even higher.⁴⁰⁸

612. Neonatal Abstinence Syndrome (NAS) has increased dramatically in California, with the rate of infants born with NAS more than tripling from 2008 to 2013.⁴⁰⁹ While the number of affected newborns rose from 1,862 in 2008 to 3,007 in 2014, that number jumped by another 21 percent in 2015.⁴¹⁰ This is despite a steady decline in the overall number of births in California during that same time.⁴¹¹



⁴⁰⁵ *Id.*

⁴⁰⁶ *Id.*

⁴⁰⁷ *Id.*

⁴⁰⁸ *Id.*

⁴⁰⁹ California Child Welfare Co-Investment Partnership, *supra* at 5.

⁴¹⁰ Clark, *supra*.

⁴¹¹ *Id.*

1 613. Reports from California’s Office of Statewide Health Planning, which
 2 collects data from licensed health care facilities, have shown a 95 percent increase
 3 between 2008 and 2015 of newborns affected by drugs transmitted via placenta or
 4 breast milk.⁴¹²

5 614. The opioid epidemic has also had an impact on crime in California.
 6 Pharmacy robberies have gone up by 163 percent in California over the last two
 7 years, according to the DEA. The DEA recorded 90 incidents in 2015, 154 in 2016
 8 and, through mid-November of 2017, that number had climbed to 237.⁴¹³ Most
 9 perpetrators were after prescription opioids.⁴¹⁴ In addition, fentanyl seizures at
 10 California ports increased 266 percent in fiscal year 2017.⁴¹⁵

11 615. The opioid epidemic is particularly devastating in Plaintiffs’
 12 Community.

13 616. In 2016, the County had an opioid overdose death rate of 8.1 per
 14 100,000 people.⁴¹⁶ In 2015, the County’s opioid overdose death rate was in the
 15 second highest quartile in the State.⁴¹⁷

19 ⁴¹² California Child Welfare Co-Investment Partnership, *supra*.

20 ⁴¹³ Ed Fletcher, “What’s behind the spike in drug store robberies?” *The Sacramento*
 21 *Bee*, Dec. 8, 2017 (available at
 22 <http://www.sacbee.com/news/local/crime/article188636384.html> (last visited
 March 2, 2018)).

23 ⁴¹⁴ *Id.*

24 ⁴¹⁵ United State Department of Justice, The United States Attorney’s Office,
 Southern District of California, *U.S. Attorney Appoints Opioid Coordinators* (Feb.
 8, 2018) available at [https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-](https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-opioid-coordinators)
 opioid-coordinators (last visited March 2, 2018).

25 ⁴¹⁶ California Department of Public Health, *California Opioid Overdose*
 26 *Surveillance Dashboard*, available at https://pdop.shinyapps.io/ODdash_v1/ (last
 visited April 20, 2018) (Yuba County specific page).

27 ⁴¹⁷ Public Health Institute, Tackling An Epidemic: An Assessment of the California
 Opioid Safety Coalitions Network, at p. 11, available at
 28 [https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27tt](https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27tt dpzxmbclj7cxq99alz.pdf)
 dpzxmbclj7cxq99alz.pdf (last visited April 20, 2018).

1 617. In 2016, an estimated 5.9 percent of the population aged 12 and up in
2 Yuba County misused opioids – that’s over 4,000 people – and over one percent
3 (728 people) had an opioid use disorder.⁴¹⁸

4 618. From 2012-2014, the County suffered 22 deaths due to drug overdoses
5 for a drug overdose mortality rate of 10 deaths per 100,000 residents.⁴¹⁹

6 619. The CDC has tracked prescription rates per county in the United
7 States, identifying the geographic “hotspots” for rates of opioid prescriptions.⁴²⁰
8 The CDC has calculated the geographic distribution at county levels of opioid
9 prescriptions dispensed per 100 persons,⁴²¹ revealing that Yuba County has been a
10 consistent hotspot over at least the past decade.

11 620. The CDC’s statistics prove that the opioid prescription rates in Yuba
12 County have exceeded any legitimate medical, scientific, or industrial purpose. The
13 overall opioid prescribing rate in 2016 was 66.5 prescriptions per 100 people and
14 44.8 in California.⁴²² However, in Yuba County, California, the 2016 prescription
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21 ⁴¹⁸ Lisa Clemans-Cope, Marni Epstein, and Doug Wissoker, “County-Level
22 Estimates of Opioid Use Disorder and Treatment Needs in California,” *The Urban
Institute*, March 19, 2018, available at
<https://www.urban.org/sites/default/files/yuba.pdf> (last visited April 20, 2018).

23 ⁴¹⁹ County Health Rankings & Roadmaps, Drug overdose deaths, available at
24 [http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/dat](http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/data)
a (last visited April 20, 2018).

25 ⁴²⁰ U.S. Prescribing Rate Maps, CDC, available at
26 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
2017).

27 ⁴²¹ *Id.*

28 ⁴²² *Id.* See also U.S. State Prescribing Rates, 2016, available at
<https://www.cdc.gov/drugoverdose/maps/rxstate2016.html> (last visited April 18,
2018).

1 rate was 83.2 per 100 people.⁴²³ This is down from the 2015 prescribing rate for
 2 Yuba County which was 92.0 per 100 people.⁴²⁴

3 621. Unfortunately, the 2015 and 2016 high rates of opioid prescriptions
 4 were not an aberration for Yuba County. Consistently, the opioid prescribing rates
 5 in Yuba County have been among the highest in the state, significantly greater than
 6 the national and state averages, and often more than one prescription per person
 7 living in the County. Compared to a national average of 75.6 opioid prescriptions
 8 per 100 people in 2014⁴²⁵ and 52.7 in California,⁴²⁶ the Yuba County opioid
 9 prescription rate was 96.2 per 100 people.⁴²⁷ In 2013, the national average was 78.1
 10 opioid prescriptions per 100 people,⁴²⁸ but the opioid prescription rate in Yuba
 11 County was 105.5 per 100 people – more than one prescription for every man,
 12 woman and child in Yuba County.⁴²⁹ Compared to a national average of 81.3 opioid
 13
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16 ⁴²³ U.S. County Prescribing Rates, 2016, (reporting for “Yuba, CA” here and
 17 below) CDC available at
 18 <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html> (last visited April 18,
 2018).

19 ⁴²⁴ U.S. County Prescribing Rates, 2015, CDC, available at
 20 <https://www.cdc.gov/drugoverdose/maps/rxcounty2015.html> (last visited April 18,
 2018).

21 ⁴²⁵ U.S. Prescribing Rate Maps, CDC, available at
 22 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

23 ⁴²⁶ U.S. State Prescribing Rates, 2014, CDC, available at
 24 <https://www.cdc.gov/drugoverdose/maps/rxstate2014.html> (last visited Dec. 11,
 2017).

25 ⁴²⁷ U.S. County Prescribing Rates, 2014, CDC, available at
 26 <https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html> (last visited April 18,
 2018).

27 ⁴²⁸ U.S. Prescribing Rate Maps, CDC, available at
 28 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

⁴²⁹ U.S. County Prescribing Rates, 2013, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxcounty2013.html> (last visited April 18,
 2018).

1 prescriptions per 100 people in 2012,⁴³⁰ the opioid prescription rate in Yuba County
 2 was 108 per 100 people that year.⁴³¹ In 2011, the national average was 80.9 opioid
 3 prescriptions per 100 people,⁴³² but the opioid prescription rate in Yuba County was
 4 108.8 per 100 people.⁴³³ Compared to a national average of 81.2 opioid
 5 prescriptions per 100 people in 2010,⁴³⁴ the Yuba County opioid prescription rate
 6 was 111.2 per 100 people – an all-time high for Yuba County.⁴³⁵ In 2009, the
 7 national average was 79.5 opioid prescriptions per 100 people,⁴³⁶ but the rate in
 8 Yuba County was 98.5.⁴³⁷ Compared to a national average of 78.2 opioid
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 15 ⁴³⁰ U.S. Prescribing Rate Maps, CDC, available at
 16 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

17 ⁴³¹ U.S. County Prescribing Rates, 2012, CDC, available at
 18 <https://www.cdc.gov/drugoverdose/maps/rxcounty2012.html> (last visited April 18,
 2018).

19 ⁴³² U.S. Prescribing Rate Maps, CDC, available at
 20 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

21 ⁴³³ U.S. County Prescribing Rates, 2011, CDC, available at
 22 <https://www.cdc.gov/drugoverdose/maps/rxcounty2011.html> (last visited April 18,
 2018).

23 ⁴³⁴ U.S. Prescribing Rate Maps, CDC, available at
 24 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

25 ⁴³⁵ U.S. County Prescribing Rates, 2010, CDC, available at
 26 <https://www.cdc.gov/drugoverdose/maps/rxcounty2010.html> (last visited April 18,
 2018).

27 ⁴³⁶ U.S. Prescribing Rate Maps, CDC, available at
 28 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

⁴³⁷ U.S. County Prescribing Rates, 2009, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxcounty2009.html> (last visited April 18,
 2018).

1 prescriptions per 100 people in 2008⁴³⁸ and 55.1 in California,⁴³⁹ the Yuba County
 2 rate was 84 per 100 people.⁴⁴⁰

3 **2. Relief Sought.**

4 622. The RICO Marketing Defendants' violations of law and their pattern
 5 of racketeering activity directly and proximately caused The County injury in its
 6 business and property. The RICO Marketing Defendants' pattern of racketeering
 7 activity logically, substantially and foreseeably caused an opioid epidemic. The
 8 County's injuries, as described below, were not unexpected, unforeseen or
 9 independent.⁴⁴¹ Rather, as Plaintiffs allege, the RICO Marketing Defendants knew
 10 that the opioids were unsuited to treatment of long-term chronic, non-acute, and
 11 non-cancer pain, or for any other use not approved by the FDA, and knew that
 12 opioids were highly addictive and subject to abuse.⁴⁴² Nevertheless, the RICO
 13 Marketing Defendants engaged in a scheme of deception, that utilized the mail and
 14 wires as part of their fraud, in order to increase sales of their opioid products.

15 623. It was foreseeable and expected that a massive marketing campaign
 16 utilized by the RICO Marketing Defendants that misrepresented the non-addictive
 17 and effective use of prescription opioids for purposes for which they are not suited
 18 and not approved by the FDA would lead to a nationwide opioid epidemic.⁴⁴³ It
 19 was also foreseeable and expected that the RICO Marketing Defendants' marketing
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21 ⁴³⁸ U.S. Prescribing Rate Maps, CDC, available at
 22 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

23 ⁴³⁹ U.S. State Prescribing Rates, 2008, CDC, available at
 24 <https://www.cdc.gov/drugoverdose/maps/rxstate2008.html> (last visited Dec. 11,
 2017).

25 ⁴⁴⁰ U.S. County Prescribing Rates, 2008, CDC, available at
 26 <https://www.cdc.gov/drugoverdose/maps/rxcounty2008.html> (last visited April 18,
 2018).

27 ⁴⁴¹ *Traveler's Property Casualty Company of America v. Actavis, Inc.*, 22 Cal.
 Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

28 ⁴⁴² *Id.*

⁴⁴³ *Id.*

1 campaign would lead to increased opioid addiction and overdose.⁴⁴⁴ The County's
2 injuries were logically, foreseeable, and substantially caused by the opioid epidemic
3 that the RICO Marketing Defendants created.

4 624. Specifically, the RICO Marketing Defendants' predicate acts and
5 pattern of racketeering activity caused the opioid epidemic which has injured The
6 County in the form of substantial losses of money and property that logically,
7 directly and foreseeably arise from the opioid-addiction epidemic. The County's
8 injuries, as alleged throughout this complaint, and expressly incorporated herein by
9 reference, include:

- 10 a. Losses caused by purchasing and/or paying reimbursements for the RICO
11 Marketing Defendants' prescription opioids, that The County would not
12 have paid for or purchased but for the RICO Marketing Defendants'
13 conduct;
- 14 b. Losses caused by the decrease in funding available for The County's
15 public services for which funding was lost because it was diverted to other
16 public services designed to address the opioid epidemic;
- 17 c. Costs for providing healthcare and medical care, additional therapeutic,
18 and prescription drug purchases, and other treatments for patients
19 suffering from opioid-related addiction or disease, including overdoses
20 and deaths;
- 21 d. Costs of training emergency and/or first responders in the proper
22 treatment of drug overdoses;
- 23 e. Costs associated with providing police officers and other first responders
24 with Naloxone – an opioid antagonist used to block the deadly effects of
25 opioids in the context of overdose;
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⁴⁴⁴ *Id.*

- 1 f. Costs associated with emergency responses by police officers and others
- 2 to opioid overdoses;
- 3 g. Costs for providing mental-health services, treatment, counseling,
- 4 rehabilitation services, and social services to victims of the opioid
- 5 epidemic and their families;
- 6 h. Costs for providing treatment of infants born with opioid-related medical
- 7 conditions, or born addicted to opioids due to drug use by mother during
- 8 pregnancy;
- 9 i. Costs associated with law enforcement and public safety relating to the
- 10 opioid epidemic, including but not limited to attempts to stop the flow of
- 11 opioids into local communities, to arrest and prosecute street-level
- 12 dealers, to prevent the current opioid epidemic from spreading and
- 13 worsening, and to deal with the increased levels of crimes that have
- 14 directly resulted from the increased homeless and drug-addicted
- 15 population;
- 16 j. Costs associated with increased burden on the County's judicial system,
- 17 including increased security, increased staff, and the increased cost of
- 18 adjudicating criminal matters due to the increase in crime directly
- 19 resulting from opioid addiction;
- 20 k. Costs associated with providing care for children whose parents suffer
- 21 from opioid-related disability or incapacitation;
- 22 l. Loss of tax revenue due to the decreased efficiency and size of the
- 23 working population in Plaintiffs' Community;
- 24 m. Losses caused by diminished property values in neighborhoods where the
- 25 opioid epidemic has taken root; and
- 26 n. Losses caused by diminished property values in the form of decreased
- 27 business investment and tax revenue.
- 28

625. The County's injuries were proximately caused by the RICO Marketing Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of The County's injuries. But for the opioid-addiction epidemic created by the RICO Marketing Defendants' conduct, The County would not have lost money or property.

626. The County's injuries were directly caused by the RICO Marketing Defendants' pattern of racketeering activities.

627. The County is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

628. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT IV

RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT

18 U.S.C. 1961, et seq.

(Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis,

McKesson, Cardinal, and AmerisourceBergen)

(The “Opioid Diversion Enterprise”)

629. Plaintiff, The County, hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

630. The County brings this Claim against the following Defendants, as defined above: Purdue, Cephalon, Endo, Mallinckrodt, Actavis (the “Manufacturer Defendants”), McKesson, Cardinal, and AmerisourceBergen (the “Distributor Defendants”) (collectively, for purposes of this Claim, the “RICO Diversion Defendants”).

631. The RICO Diversion Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise as defined in 18 U.S.C. § 1961(4). Alternatively, the RICO Diversion Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4). Specifically, each of the RICO Diversion Defendants was a member of the Healthcare Distribution Alliance (the “HDA”)⁴⁴⁵ which is a distinct legal entity that satisfies the definition of a RICO enterprise because it is a non-profit corporation and, therefore, and “enterprise” within the definition set out in 18 U.S.C. § 1961(4). On information and belief, each of the RICO Diversion Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to this cause of action. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

632. For over a decade, the RICO Diversion Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Diversion Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. As “registrants” under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”), the RICO Diversion Defendants operated and continue to operate within a “closed-system.” The CSA restricts the RICO Diversion Defendants’ ability to manufacture or distribute Schedule II substances like opioids by: (1) requiring them to make sales within a limited quota set by the

⁴⁴⁵ Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

1 DEA for the overall production of Schedule II substances like opioids; (2) register
 2 to manufacture or distribute opioids; (3) maintain effective controls against
 3 diversion of the controlled substances that they manufacturer or distribute; and (4)
 4 design and operate a system to identify suspicious orders of controlled substances,
 5 halt such unlawful sales, and report them to the DEA.

6 633. The closed-system created by the CSA, and the establishment of
 7 quotas, was specifically intended to reduce or eliminate the diversion of Schedule
 8 II substances like opioids from “legitimate channels of trade” to the illicit market
 9 by controlling the “quantities of the basic ingredients needed for the manufacture
 10 of [controlled substances].”⁴⁴⁶

11 634. Finding it impossible to legally achieve their ever increasing sales
 12 ambitions, members of the Opioid Diversion Enterprise (defined below) engaged in
 13 the common purpose of fraudulently increasing the quotas that governed the
 14 manufacture and distribution of their prescription opioids. The RICO Diversion
 15 Defendants formed and pursued their common purpose through the many personal
 16 interactions that they had, confidentially, in organizations like the Pain Care Forum
 17 and the Healthcare Distribution Alliance.

18 635. The RICO Diversion Defendants’ common purpose and fraudulent
 19 scheme to unlawfully increase the DEA quotas violated the RICO Act in two ways.
 20 First, the RICO Diversion Defendants violated the RICO Act because they engaged
 21 in the felonious manufacture, buying selling, or otherwise dealing in controlled
 22 substances that are punishable by law in the United States. Specifically, the RICO
 23 Diversion Defendants “furnish[ed] false or fraudulent material information in, or
 24 omit[ted] material information from, applications, reports, records, and other
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26 ⁴⁴⁶ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi
 27 before the Caucus on International Narcotics Control, United States Senate, May 5,
 28 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

document required to be made, kept, and filed under 21 U.S.C. §§ 801, et seq.”, in violation of 21 U.S.C. § 843(b), which is a felony. Second, the RICO Diversion Defendants violated the RICO Act by engaging in mail and wire fraud. The RICO Diversion Defendants common purpose and fraudulent scheme was intended to, and did, utilize interstate mail and wire facilities for the commission of their fraud in violation 18 U.S.C. §§ 1341 (mail fraud) and 1343 (wire fraud).

636. The RICO Diversion Defendants’ fraudulent scheme arises at the intersection between the quotas governing the RICO Diversion Defendants’ prescription opioids and the RICO Diversion Defendants’ duty to identify, report, and halt suspicious orders of controlled substances. The RICO Diversion Defendants’ formed an enterprise with the intent to fraudulently increase the quotas for prescription opioids by refusing to identify, report and halt suspicious orders, thereby omitting both the fact and the RICO Diversion Defendants’ knowledge of widespread diversion of prescription opioids into illegitimate channels.

637. The RICO Diversion Defendants engaged in systematic and fraudulent acts as part of the Opioid Diversion Enterprise, that furnished false or fraudulent material information in, and omitted material information from their applications, reports, records and other documents that the RICO Defendants were required to make, keep and/or file. Furthermore, the RICO Diversion Defendants engaged in systematic and fraudulent acts as part of the Opioid Diversion Enterprise that were intended to and actually did utilize the mail and wire facilities of the United States and California, including refusing to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.⁴⁴⁷

⁴⁴⁷ 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

1 638. Through the RICO Diversion Defendants' scheme, members of the
2 Opioid Diversion Enterprise repeatedly requested increases of the quotas governing
3 the manufacture, sale and distribution of prescription opioids, misrepresented that
4 they were complying with their duties under the CSA, furnished false or fraudulent
5 material information in, and omitted material information from their applications,
6 reports, records and other documents, engaged in unlawful sales of painkillers that
7 resulted in diversion of controlled substances through suspicious orders, and
8 refused to identify or report suspicious orders of controlled substances sales to the
9 DEA.⁴⁴⁸ Defendants' refusal to report suspicious orders resulted in artificial and
10 illegal increases in the annual production quotas for opioids allowed by the DEA.
11 The end result of the RICO Diversion Defendants' fraudulent scheme and common
12 purpose was continually increasing quotas that generated obscene profits and, in
13 turn, fueled an opioid epidemic.

14 639. The RICO Diversion Defendants' illegal scheme was hatched by an
15 enterprise between the Manufacturer Defendants and the Distributor Defendants,
16 and executed in perfect harmony by each of them. In particular, each of the RICO
17 Diversion Defendants were associated with, and conducted or participated in, the
18 affairs of the Opioid Diversion Enterprise, whose common purpose was
19 fraudulently increase the quotas governing the manufacture and sale of prescription
20 opioids.

21 640. The success of the RICO Diversion Defendants' scheme allowed them
22 to unlawfully increase and/or maintain high production quotas and, as a direct
23 result, allowed them to make billions from the unlawful sale and diversion of
24 opioids.

25 641. Simultaneously, the opioid epidemic created by the RICO Diversion
26 Defendants' actions caused The County's multi-million dollar injuries. The
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28 ⁴⁴⁸ 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

County's injuries were and is a reasonably foreseeable consequence of the prescription opioid addiction epidemic that the RICO Diversion Defendants created by fraudulently increasing quotas, misrepresenting their compliance with their duties under the CSA, and allowing the widespread diversion of legally produced prescription opioids into the illicit market. As explained in detail below, the RICO Diversion Defendants' misconduct violated Section 1962(c) and the County is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

A. THE OPIOID DIVERSION ENTERPRISE.

642. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.⁴⁴⁹ The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.⁴⁵⁰ Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.⁴⁵¹ Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."⁴⁵² Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active

⁴⁴⁹ Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

⁴⁵⁰ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

⁴⁵¹ *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

⁴⁵² See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

1 participation by registrants within the drug delivery chain.⁴⁵³ All registrants --
 2 manufacturers and distributors alike -- must adhere to the specific security,
 3 recordkeeping, monitoring and reporting requirements that are designed to identify
 4 or prevent diversion.⁴⁵⁴ When registrants at any level fail to fulfill their obligations,
 5 the necessary checks and balances collapse.⁴⁵⁵ The result is the scourge of addiction
 6 that has occurred

7 643. Central to the closed-system created by the CSA was the directive that
 8 the DEA determine quotas of each basic class of Schedule I and II controlled
 9 substances each year. The quota system was intended to reduce or eliminate
 10 diversion from “legitimate channels of trade” by controlling the “quantities of the
 11 basic ingredients needed for the manufacture of [controlled substances], and the
 12 requirement of order forms for all transfers of these drugs.”⁴⁵⁶ When evaluating
 13 production quotas, the DEA was instructed to consider the following information:

- 14 a. Information provided by the Department of Health and Human Services;
- 15 b. Total net disposal of the basic class by all manufacturers;
- 16 c. Trends in the national rate of disposal of the basic class;
- 17 d. An applicant’s production cycle and current inventory position;
- 18 e. Total actual or estimated inventories of the class and of all substances
 19 manufactured from the class and trends in inventory accumulation; and
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 22 ⁴⁵³ See Statement of Joseph T. Rannazzisi before the Caucus on International
 23 Narcotics Control United States Senate, July 18, 2012 (available at
<https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>).

24 ⁴⁵⁴ Id.

25 ⁴⁵⁵ Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr.,*
Attorney General, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10,
 26 2012).

27 ⁴⁵⁶ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi
 28 before the Caucus on International Narcotics Control, United States Senate, May 5,
 2015 (available at
https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

1 f. Other factors such as: changes in the currently accepted medical use of
 2 substances manufactured for a basic class; the economic and physical
 3 availability of raw materials; yield and sustainability issues; potential
 4 disruptions to production; and unforeseen emergencies.⁴⁵⁷

5 644. It is unlawful for a registrant to manufacture a controlled substance in
 6 Schedule II, like prescription opioids, that is (1) not expressly authorized by its
 7 registration and by a quota assigned to it by DEA, or (2) in excess of a quota
 8 assigned to it by the DEA.⁴⁵⁸

9 645. At all relevant times, the RICO Diversion Defendants operated as an
 10 association-in-fact enterprise formed for the purpose of unlawfully increasing sales,
 11 revenues and profits by fraudulently increasing the quotas set by the DEA that
 12 would allow them to collectively benefit from a greater pool of prescription opioids
 13 to manufacture and distribute. In support of this common purpose and fraudulent
 14 scheme, the RICO Diversion Defendants jointly agreed to disregard their statutory
 15 duties to identify, investigate, halt and report suspicious orders of opioids and
 16 diversion of their drugs into the illicit market so that those orders would not result
 17 in a decrease, or prevent an increase in, the necessary quotas. The RICO Diversion
 18 Defendants conducted their pattern of racketeering activity in this jurisdiction and
 19 throughout the United States through this enterprise.

20 646. The opioid epidemic has its origins in the mid-1990s when, between
 21 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone
 22 increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription
 23 opioids were sold in the United States to medicate every adult in the country with a
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 26 ⁴⁵⁷ See Testimony of Joseph T. Rannazzisi before the Caucus on International
 27 Narcotics Control, United State Senate, May 5, 2015 (available at
 28 https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

⁴⁵⁸ *Id.* (citing 21 U.S.C. 842(b)).

1 dose of 5 milligrams of hydrocodone every 4 hours for 1 month.⁴⁵⁹ On information
 2 and belief, the Opioid Diversion Enterprise has been ongoing for at least the last
 3 decade.⁴⁶⁰

4 647. The Opioid Diversion Enterprise was and is a shockingly successful
 5 endeavor. The Opioid Diversion Enterprise has been conducting business
 6 uninterrupted since its genesis. However, it was not until recently that federal and
 7 state regulators finally began to unravel the extent of the enterprise and the toll that
 8 it exacted on the American public.

9 648. At all relevant times, the Opioid Diversion Enterprise: (a) had an
 10 existence separate and distinct from each RICO Diversion Defendant; (b) was
 11 separate and distinct from the pattern of racketeering in which the RICO Diversion
 12 Defendants engaged; (c) was an ongoing and continuing organization consisting of
 13 legal entities, including each of the RICO Diversion Defendants; (d) was
 14 characterized by interpersonal relationships among the RICO Diversion
 15 Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and
 16 (f) functioned as a continuing unit.. Each member of the Opioid Diversion
 17 Enterprise participated in the conduct of the enterprise, including patterns of
 18 racketeering activity, and shared in the astounding growth of profits supplied by
 19 fraudulently inflating opioid quotas and resulting sales.

20 649. The Opioid Diversion Enterprise also engaged in efforts to constrain
 21 the DEA's authority to hold the RICO Diversion Defendants liable for disregarding
 22 their duty to prevent diversion. Members of the Pain Care Forum (described in
 23 greater detail below) and the Healthcare Distribution Alliance lobbied for the
 24

25 ⁴⁵⁹ Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-
 26 urban differences in nonmedical prescription opioid use and abuse in the United
 States. Am J Public Health. 2014;104(2):e52-9.

27 ⁴⁶⁰ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug
 28 epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.),
[https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic)
shaped-policy-amid-drug-epidemic.

1 passage of legislation to weaken the DEA's enforcement authority. To this end, the
 2 Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced
 3 the DEA's ability to issue orders to show cause and to suspend and/or revoke
 4 registrations.⁴⁶¹ The HDA and other members of the Pain Care Forum contributed
 5 substantial amounts of money to political campaigns for federal candidates, state
 6 candidates, political action committees and political parties. Upon information and
 7 belief, the Pain Care Forum and its members and HDA, poured millions into such
 8 efforts.

9 650. The RICO Diversion Defendants, through their illegal enterprise,
 10 engaged in a pattern of racketeering activity that involves a fraudulent scheme to
 11 profit from the unlawful sale of prescription opioids by increasing the quotas
 12 governing the manufacture and sale of these controlled substances. In order to
 13 achieve that goal, the RICO Diversion Defendants knowingly allowed suspicious
 14 orders of controlled substances to occur unhindered while millions of opioid doses
 15 diverted into illegal markets. The end result of this strategy was exactly as the
 16 RICO Diversion Defendants intended – artificially increased quotas for the
 17 manufacture and distribution of opioids, all of which resulted in a National opioid
 18 epidemic.

19
 20
 21 ⁴⁶¹ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical
 22 Commerce, (June 13, 2016, updated July 6, 2016),
 23 [http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-](http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/)
 24 [distribution-alliance/](http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/); Lenny Bernstein & Scott Higham, *Investigation: The DEA*
 25 *Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post,
 26 Oct. 22, 2016, [https://www.washingtonpost.com/investigations/the-dea-slowed-](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html)
 27 [enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html)
 28 [7f71-11e6-8d13-d7c704ef9fd9_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html); Lenny Bernstein & Scott Higham,
Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown
Amid Opioid Crisis, Wash. Post, Mar. 6, 2017,
[https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html)
[of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html)
[a05d3c21f7cf_story.html](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV*
Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017,
[http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-](http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-)
[in-wv-amid-flood-of-pain-pills-.](http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-)

1 651. The Opioid Diversion Enterprise engaged in, and its activities affected,
2 interstate and foreign commerce because the enterprise involved commercial
3 activities across states lines, such as manufacture, sale, distribution, and shipment
4 of prescription opioids throughout the United States, and the corresponding
5 payment and/or receipt of money from such interstate sales.

6 652. Within the Opioid Diversion Enterprise, there were interpersonal
7 relationships and common communication by which the RICO Diversion
8 Defendants shared information on a regular basis. These interpersonal relationships
9 also formed the organization of the Opioid Diversion Enterprise. The Opioid
10 Diversion Enterprise used their interpersonal relationships and communication
11 network for the purpose of conducting the enterprise through a pattern of
12 racketeering activity.

13 653. Each of the RICO Diversion Defendants had systematic links to each
14 other through joint participation in trade industry organizations, contractual
15 relationships and continuing coordination of activities. The RICO Diversion
16 Defendants participated in the operation and management of the Opioid Diversion
17 Enterprise by directing its affairs, as described herein. While the RICO Diversion
18 Defendants participated in, and are members of, the enterprise, they each have a
19 separate existence from the enterprise, including distinct legal statuses, different
20 offices and roles, bank accounts, officers, directors, employees, individual
21 personhood, reporting requirements, and financial statements.

22 654. The RICO Diversion Defendants exerted substantial control over the
23 Opioid Diversion Enterprise through their membership in the Pain Care Forum, the
24 HDA, and through their contractual relationships.

25 655. The Pain Care Forum (“PCF”) has been described as a coalition of
26 drug makers, trade groups and dozens of non-profit organizations supported by
27 industry funding. The PCF recently became a national news story when it was
28

1 discovered that lobbyists for members of the PCF quietly shaped federal and state
2 policies regarding the use of prescription opioids for more than a decade.

3 656. The Center for Public Integrity and The Associated Press obtained
4 “internal documents shed[ding] new light on how drug makers and their allies
5 shaped the national response to the ongoing wave of prescription opioid abuse.”⁴⁶²
6 Specifically, PCF members spent over \$740 million lobbying in the nation’s capital
7 and in all 50 statehouses on an array of issues, including opioid-related measures.⁴⁶³

8 657. Not surprisingly, each of the RICO Diversion Defendants who stood
9 to profit from expanded prescription opioid use is a member of and/or participant
10 in the PCF.⁴⁶⁴ In 2012, membership and participating organizations included the
11 HDA (of which all RICO Defendants are members), Endo, Purdue, Actavis (i.e.,
12 Allergan), and Teva (the parent company of Cephalon).⁴⁶⁵ Each of the Manufacturer
13 Defendants worked together through the PCF to advance the interests of the
14 enterprise. But, the Manufacturer Defendants were not alone. The Distributor
15 Defendants actively participated, and continue to participate in the PCF, at a
16 minimum, through their trade organization, the HDA.⁴⁶⁶ Upon information and
17 belief, the Distributor Defendants participated directly in the PCF as well.

18
19
20 ⁴⁶² Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug
21 epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.),
[https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic)
22 [shaped-policy-amid-drug-epidemic](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic) (emphasis added).

23 ⁴⁶³ *Id.*

24 ⁴⁶⁴ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011),
25 [https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-](https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf)
26 [Meetings-Schedule-amp.pdf](https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf)

27 ⁴⁶⁵ *Id.* Upon information and belief, Mallinckrodt became an active member of the
28 PCF sometime after 2012.

⁴⁶⁶ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently
includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health,
Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source
for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for
McKesson Corporation. Executive Committee, Healthcare Distribution Alliance
(accessed on September 14, 2017),
<https://www.healthcaredistribution.org/about/executive-committee>.

1 658. Additionally, the HDA – or Healthcare Distribution Alliance – led to
 2 the formation of interpersonal relationships and an organization between the RICO
 3 Diversion Defendants. Although the entire HDA membership directory is private,
 4 the HDA website confirms that each of the Distributor Defendants and the
 5 Manufacturer Defendants named in the Complaint, including Actavis (i.e.,
 6 Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.⁴⁶⁷
 7 Additionally, the HDA and each of the Distributor Defendants, eagerly sought the
 8 active membership and participation of the Manufacturer Defendants by advocating
 9 for the many benefits of members, including “**strengthening . . . alliances**.”⁴⁶⁸

10 659. Beyond strengthening alliances, the benefits of HDA membership
 11 included the ability to, among other things, “network one on one with manufacturer
 12 executives at HDA’s members-only Business and Leadership Conference,”
 13 “networking with HDA wholesale distributor members,” “opportunities to host and
 14 sponsor HDA Board of Directors events,” “participate on HDA committees, task
 15 forces and working groups with peers and trading partners,” and “make
 16 connections.”⁴⁶⁹ Clearly, the HDA and the Distributor Defendants believed that
 17 membership in the HDA was an opportunity to create interpersonal and ongoing
 18 organizational relationships and “alliances” between the Manufacturers and
 19 Defendants.

20 660. The application for manufacturer membership in the HDA further
 21 indicates the level of connection between the RICO Defendants and the level of
 22
 23

24 ⁴⁶⁷ Manufacturer Membership, Healthcare Distribution Alliance, (accessed on
 25 September 14, 2017),
<https://www.healthcaredistribution.org/about/membership/manufacturer>.

26 ⁴⁶⁸ Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed
 27 on September 14, 2017),
<https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>.

28 ⁴⁶⁹ *Id.*

1 insight that they had into each other's businesses.⁴⁷⁰ For example, the manufacturer
 2 membership application must be signed by a "senior company executive," and it
 3 requests that the manufacturer applicant identify a key contact and any additional
 4 contacts from within its company.

5 661. The HDA application also requests that the manufacturer identify its
 6 current distribution information, including the facility name and contact
 7 information.

8 662. And, Manufacturer Members were asked to identify their "most recent
 9 year end net sales" through wholesale distributors, including the Distributor
 10 Defendants AmerisourceBergen, Cardinal Health, and McKesson and their
 11 subsidiaries.

12 663. The closed meetings of the HDA's councils, committees, task forces
 13 and working groups provided the Manufacturer and Distributor Defendants with the
 14 opportunity to work closely together, confidentially, to develop and further the
 15 common purpose and interests of the enterprise.

16 664. The HDA also offers a multitude of conferences, including annual
 17 business and leadership conferences. The HDA, and the Distributor Defendants
 18 advertise these conferences to the Manufacturer Defendants as an opportunity to
 19 "bring together high-level executives, thought leaders and influential managers . . .
 20 to hold strategic business discussions on the most pressing industry issues."⁴⁷¹ The
 21 conferences also gave the Manufacturer and Distributor Defendants "unmatched
 22 opportunities to network with [their] peers and trading partners at all levels of the
 23

24 ⁴⁷⁰ Manufacturer Membership Application, Healthcare Distribution Alliance,
 25 (accessed on September 14, 2017),
 26 <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

27 ⁴⁷¹ Business and Leadership Conference – Information for Manufacturers,
 28 Healthcare Distribution Alliance <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers> (last accessed on September 14, 2017).

1 healthcare distribution industry.”⁴⁷² The HDA and its conferences were significant
 2 opportunities for the Manufacturer and Distributor Defendants to interact at a high-
 3 level of leadership. It is clear that the Manufacturer Defendants embraced this
 4 opportunity by attending and sponsoring these events.⁴⁷³

5 665. Third, the RICO Diversion Defendants maintained their interpersonal
 6 relationships by working together, through contractual chargeback arrangements,
 7 to exchanging sales information and drive the unlawful sales of their opioids. To
 8 this end, the Manufacturer Defendants engaged in an industry-wide practice of
 9 paying rebates to the Distributor Defendants for sales of prescription opioids.⁴⁷⁴

10 666. For example, the *Washington Post* reported that “[o]n Aug. 23, 2011,
 11 DEA supervisors met with Mallinckrodt executives at the agency’s headquarters in
 12 Arlington, Va., the day a rare 5.8-magnitude earthquake hit the Washington region.
 13 People involved in the case still call the gathering ‘the earthquake meeting.’ DEA
 14 officials showed the company the remarkable amounts of its oxycodone going to
 15 distributors and the number of arrests being made for oxycodone possession and
 16 distribution on the street, according to one participant in the meeting who also spoke
 17 on the condition of anonymity because the case is pending.”⁴⁷⁵

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 19 ⁴⁷² *Id.*

20 ⁴⁷³ 2015 Distribution Management Conference and Expo, Healthcare Distribution
 21 Alliance, [https://www.healthcaredistribution.org/events/2015-distribution-](https://www.healthcaredistribution.org/events/2015-distribution-management-conference)
 22 management-conference (last accessed on September 14, 2017).

23 ⁴⁷⁴ Lenny Bernstein & Scott Higham, The government’s struggle to hold opioid
 24 manufacturers accountable, *The Washington Post*, (April 2, 2017),
 25 [https://www.washingtonpost.com/graphics/investigations/dea-](https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356)
 26 [mallinckrodt/?utm_term=.b24cc81cc356](https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356); *see also*, Letter from Sen. Claire
 27 McCaskill, (July 27, 2017),
 28 [https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-](https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png)
 letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017),
[https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-](https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png)
 letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017),
<https://www.mccaskill.senate.gov/opioid-investigation>; Purdue Managed Markets,
 Purdue Pharma, (accessed on September 14, 2017),
<http://www.purduepharma.com/payers/managed-markets/>.

⁴⁷⁵ [https://www.washingtonpost.com/graphics/investigations/dea-](https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.f336835fd5da)
[mallinckrodt/?utm_term=.f336835fd5da](https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.f336835fd5da)

1 667. “Three weeks after the Aug. 23 meeting, Mallinckrodt notified 43 of
2 its distributors that they would no longer receive rebates from the company if they
3 continued to supply certain pharmacies whose orders appeared to be suspicious.”⁴⁷⁶

4 668. “On Nov. 30, 2011, the DEA served a subpoena on Mallinckrodt,
5 demanding documents related to its suspicious-order-monitoring program,
6 according to the company’s filings with the Securities and Exchange Commission.
7 The subpoena brought a windfall of information. The DEA gained access to data
8 from Mallinckrodt’s rebate or ‘chargeback’ program, an industry-wide practice that
9 provides reimbursements to wholesale distributors. That information and other
10 records showed where Mallinckrodt’s oxycodone was going — from the company
11 to its network of distributors to retailers down the chain.”⁴⁷⁷

12 669. In addition, the Distributor Defendants and Manufacturer Defendants
13 participated, through the HDA, in Webinars and other meetings designed to
14 exchange detailed information regarding their prescription opioid sales, including
15 purchase orders, acknowledgements, ship notices, and invoices.⁴⁷⁸ For example, on
16 April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange
17 business transactions between distributors and manufacturers...”:

26 ⁴⁷⁶ Id.

27 ⁴⁷⁷ Id.

28 ⁴⁷⁸ Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017),
<https://www.healthcaredistribution.org/resources/webinar-leveraging-edi>.

Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set



(Webinar held: April 27, 2011) Using EDI to accurately and efficiently exchange business transactions (i.e., purchase orders, acknowledgements, ship notices, invoices, etc.) between distributors and manufacturers in the healthcare supply chain is critical. The development and use of voluntary guidelines for specific EDI standards provide industry trading partners with a means to effectively convey the necessary information.

Hear updates on HDMA's Order-to-Cash Guidelines for Electronic Data Interchange (EDI) in the Healthcare Product Supply Chain, including the 810 Invoice; 850 Purchase Order; 855 Purchase Order Acknowledgement; and the 856 Ship Notice/Manifest.

670. On information and belief, the Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

671. And, through the HDA, Manufacturer Members were asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants as follows:

Company	Most Recent Year End Net Sales
Henry Schein, Inc.	
Henry Schein Distribution Centers (7)	
Hospital Pharmaceutical Consulting (1)	
KeySource Medical, Inc. (1)	
Louisiana Wholesale Drug Co. Inc. (1)	
McKesson Corporation (71)	
McKesson Supply Solutions (25)	
McKesson Canada (12)	
McKesson Corporation (4)	
McKesson Specialty Health (1)	
McKesson Strategic Redistribution Center (1)	
McKesson Medical Surgical (1)	
Physician Sales & Service (PSS) (25)	
US Oncology (1)	
DeVictoria Healthcare, Inc. PR (1)	
Miami-Luken, Inc. (1)	
Morris & Dickson Co., LLC (1)	
Mutual Wholesale Drug Co. (1)	
PBA Health (1)	
Prescription Supply, Inc. (1)	
Prodigy Health Supplier Corporation (1)	
Quality Care Products, LLC (1)	
RDC (3)	
R&S Northeast LLC (2)	
Richie Pharmacal Co., LLC (1)	
Seacoast Medical LLC (1)	
Smith Drug Company, Div. JM Smith Corporation (4)	
Burlington Drug Company, Inc. (1)	
Smith Drug Company, Div. JM Smith Corporation (3)	
Top Rx (4)	
Value Drug Company (1)	
VaxServe (1)	
TOTAL SALES (millions)	\$ 0

1 672. The contractual relationships among the RICO Defendants also
 2 include vault security programs. The RICO Diversion Defendants are required to
 3 maintain certain security protocols and storage facilities for the manufacture and
 4 distribution of their opiates. Upon information and belief, the manufacturers
 5 negotiated agreements whereby the Manufacturers installed security vaults for
 6 Distributors in exchange for agreements to maintain minimum sales performance
 7 thresholds. Upon information and belief, these agreements were used by the RICO
 8 Diversion Defendants as a tool to violate their reporting and diversion duties in
 9 order to reach the required sales requirements.

10 673. Taken together, the interaction and length of the relationships between
 11 and among the Manufacturer and Distributor Defendants reflects a deep level of
 12 interaction and cooperation between two groups in a tightly knit industry. The
 13 Manufacturer and Distributor Defendants were not two separate groups operating
 14 in isolation or two groups forced to work together in a closed system. The RICO
 15 Diversion Defendants operated together as a united entity, working together on
 16 multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA
 17 and the Pain Care Forum are but two examples of the overlapping relationships, and
 18 concerted joint efforts to accomplish common goals and demonstrates that the
 19 leaders of each of the RICO Diversion Defendants were in communication and
 20 cooperation.

21 674. Alternatively, the RICO Diversion Defendants were members of a
 22 legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which
 23 the RICO Diversion Defendants conducted their pattern of racketeering activity in
 24 this jurisdiction and throughout the United States. As alleged, the Healthcare
 25 Distribution Alliance (the “HDA”)⁴⁷⁹ is a distinct legal entity that satisfies the

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 28 ⁴⁷⁹ Health Distribution Alliance, History, Health Distribution Alliance, (last
 accessed on September 15, 2017),
<https://www.healthcaredistribution.org/about/hda-history>.

1 definition of a RICO enterprise because it is a corporation formed under the laws
2 of the District of Columbia, doing business in Virginia. As such, the HDA qualifies
3 as an “enterprise” within the definition set out in 18 U.S.C. § 1961(4).

4 675. On information and belief, each of the RICO Diversion Defendants is
5 a member, participant, and/or sponsor of the HDA, and has been since at least 2006,
6 and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in
7 the pattern of racketeering activity that gives rise to the Count.

8 676. Each of the RICO Diversion Defendants is a legal entity separate and
9 distinct from the HDA. Additionally, the HDA serves the interests of distributors
10 and manufacturers beyond the RICO Diversion Defendants. Therefore, the HDA
11 exists separately from the Opioid Diversion Enterprise, and each of the RICO
12 Diversion Defendants exists separately from the HDA. Therefore, the HDA may
13 serve as a RICO enterprise.

14 **B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.**

15 677. During the time period alleged in this Complaint, the RICO Diversion
16 Defendants exerted control over, conducted and/or participated in the Opioid
17 Diversion Enterprise by fraudulently claiming that they were complying with their
18 duties under the CSA to identify, investigate and report suspicious orders of opioids
19 in order to prevent diversion of those highly addictive substances into the illicit
20 market, and to halt such unlawful sales, so as to increase production quotas and
21 generate unlawful profits, as follows:

22 678. Defendants disseminated false and misleading statements to state and
23 federal regulators claiming that (1) the quotas for prescription opioids should be
24 increased, (2) they were complying with their obligations to maintain effective
25 controls against diversion of their prescription opioids, (3) they were complying
26 with their obligations to design and operate a system to disclose to the registrant
27 suspicious orders of their prescription opioids, (4) they were complying with their
28 obligation to notify the DEA of any suspicious orders or diversion of their

1 prescription opioids and (5) they did not have the capability to identify suspicious
 2 orders of controlled substances despite their possession of national, regional, state,
 3 and local prescriber- and patient-level data that allowed them to track prescribing
 4 patterns over time, which the Defendants obtained from data companies, including
 5 but not limited to: IMS Health, QuintilesIMS, Iqvia, Pharmaceutical Data Services,
 6 Source Healthcare Analytics, NDS Health Information Services, Verispan,
 7 Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health
 8 Science, and all of their predecessors or successors in interest (the “Data Vendors”).

9 679. The RICO Diversion Defendants applied political and other pressure
 10 on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of
 11 prescription opioids and lobbied Congress to strip the DEA of its ability to
 12 immediately suspend registrations pending investigation by passing the “Ensuring
 13 Patient Access and Effective Drug Enforcement Act.”⁴⁸⁰

14 680. The Distributor Defendants developed “know your customer”
 15 questionnaires and files. This information, compiled pursuant to comments from
 16 the DEA in 2006 and 2007 was intended to help the RICO Diversion Defendants
 17 identify suspicious orders or customers who were likely to divert prescription
 18 opioids.⁴⁸¹ On information and belief, the “know your customer” questionnaires
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20 ⁴⁸⁰ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical
 21 Commerce, (June 13, 2016, updated July 6, 2016),
 22 [http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-](http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/)
 23 [distribution-alliance/](http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/); Lenny Bernstein & Scott Higham, *Investigation: The DEA*
 24 *Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post,
 25 Oct. 22, 2016, [https://www.washingtonpost.com/investigations/the-dea-slowed-](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html)
 26 [enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html)
 27 [7f71-11e6-8d13-d7c704ef9fd9_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html); Lenny Bernstein & Scott Higham,
 28 *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown*
 29 *Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017,
 30 [https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html)
 31 [of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html)
 32 [a05d3c21f7cf_story.html](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html); Eric Eyre, *DEA Agent: “We Had no Leadership” in WV*
 33 *Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017,
 34 [http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-](http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-)
 35 [in-wv-amid-flood-of-pain-pills-.](http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-)

36 ⁴⁸¹ Suggested Questions a Distributor should ask prior to shipping controlled
 37 substances, Drug Enforcement Administration (available at

1 informed the RICO Diversion Defendants of the number of pills that the pharmacies
 2 sold, how many non-controlled substances are sold compared to controlled
 3 substances, whether the pharmacy buys from other distributors, the types of medical
 4 providers in the area, including pain clinics, general practitioners, hospice facilities,
 5 cancer treatment facilities, among others, and these questionnaires put the recipients
 6 on notice of suspicious orders.

7 681. The RICO Diversion Defendants purchased nationwide, regional,
 8 state, and local prescriber- and patient-level data from the Data Vendors that
 9 allowed them to track prescribing trends, identify suspicious orders, identify
 10 patients who were doctor shopping, identify pill mills, etc. The Data Vendors'
 11 information purchased by the RICO Diversion Defendants allowed them to view,
 12 analyze, compute, and track their competitors sales, and to compare and analyze
 13 market share information.⁴⁸²

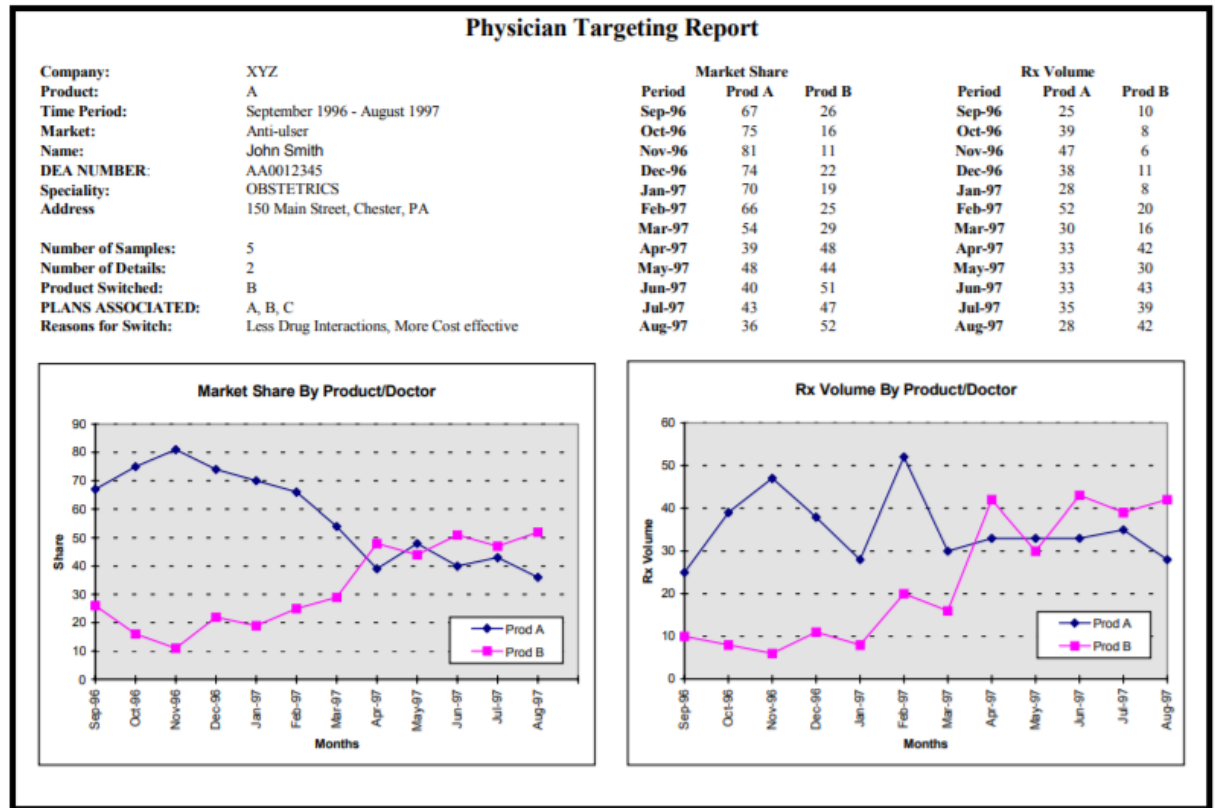
14 682. IMS, for example, IMS provided the RICO Diversion Defendants with
 15 reports detailing prescriber behavior and the number of prescriptions written
 16 between competing products.⁴⁸³

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 22 https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production
 23 Diversion: Beyond the PDMA, Purdue Pharma and McGuireWoods LLC,
 24 (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

25 ⁴⁸² A Verispan representative testified that the RICO Defendants use the
 26 prescribing information to “drive market share.” *Sorrell v. IMS Health Inc.*, 2011
 27 WL 661712, *9-10 (Feb. 22, 2011).

28 ⁴⁸³ Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned*
 27 *a Mountain of Data into a Few Information-rich Molehills*, (accessed on February
 15, 2018),
<http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf>, Figure 2 at p.3.

Figure 2:



683. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the RICO Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.⁴⁸⁴

⁴⁸⁴ *Sorrell v. IMS Health Inc.*, 2011 WL 705207, *467-471 (Feb. 22, 2011).

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1. The Prescriber Roster shows Prescriber demographics, prescribing information and indicator arrows

Territory : 1102 Prescriber				Weekly Prescriber TR			
	Trend	Specialty	Product	WEEK Feb-03-06	WEEK Jan-27-06	WEEK Jan-20-06	WEEK Jan-13-06
Territory : 1102 – TOTAL			PRODUCT A	46	64	58	88
			PRODUCT B	292	253	247	278
			PRODUCT C	55	56	56	58
			PRODUCT D	36	28	34	33
			PRODUCT E	7	9	2	9
			PRODUCT F	1	3	5	0
Doctor A		IM	PRODUCT A	4	1	1	1
			PRODUCT B	2	2	2	3
			PRODUCT C	0	2	0	0
			PRODUCT D	0	0	0	0
			PRODUCT E	0	0	0	0
			PRODUCT F	0	0	0	0
Doctor B		GE	PRODUCT A	3	1	1	2
			PRODUCT B	5	4	7	2
			PRODUCT C	0	1	0	0
			PRODUCT D	0	0	0	0
			PRODUCT E	0	1	0	1
			PRODUCT F	0	0	0	0
Doctor C		GE	PRODUCT A	3	1	2	0
			PRODUCT B	4	5	0	3
			PRODUCT C	0	1	1	0
			PRODUCT D	0	1	0	2
			PRODUCT E	0	0	0	0
			PRODUCT F	0	0	0	0

* * *

3. Territory Summary Report shows Prescriber Roster information aggregated at a territory level

Territory Summary

Name	Spec	Zip	Product A NRX	Product A MM Share	Product A Rank	Market NRX	Market Rank
ABNEY, RAY C.	P	05302	6	10.7%	43	56	38
ALLISTER, ROBERT	P	03820	6	18.8%	43	32	63
ALTMAN, LEE S.	P	01655	34	14.0%	3	247	3
BALLARD, HARLOW	P	05801	0	0.0%	93	8	96
BARNEY, CHRISTINE A.	P	03766	6	26.1%	43	23	85
BARTON, GAIL	P	03755	13	32.5%	18	40	50
BERNSTEIN, RICHARD A.	P	05401	0	0.0%	93	14	94
BOHNERI, MICHAEL	P	03060	3	4.5%	73	66	29
BOSTIC, JEFFERY O.	CHP	03079	5	10.9%	55	45	44
BREITHOLTZ, TIMOTHY	P	03870	13	34.2%	18	38	52
BROWN, KENNETH	P	03941	4	10.0%	61	40	50
BUCHANAN, KEVIN	P	05701	5	16.1%	55	31	70
CARMAN, MEGAN W.	P	03246	10	12.3%	28	81	18
CARSEN, MARJORIA	P	05701	6	18.2%	43	33	59
CATPANO-FRIEDMAN, LISA	P	05201	5	8.6%	43	70	25
CLARKE-RUBIN, LORNA	P	12901	8	24.2%	32	33	59
COHEN, DEVRA H.	CHP	03060	3	6.5%	73	46	44
COLE, STEPHEN A.	P	05101	5	13.2%	55	38	52
COTTON, PAUL G.	P	05401	13	28.3%	18	46	44
CUSI, PRISCILLA M.	P	03104	17	7.9%	14	215	5
DAVISON, MARTHA F.	P	03110	14	11.3%	16	124	8
DEJONG, JACOB	P	03067	0	0.0%	93	21	87
DELFAUSSE, PETER O.	P	03301	6	35.3%	43	17	90
DENNETT, DOUGLAS E.	CHP	05401	0	0.0%	93	33	59
DEPPE, SUSAN L.	P	05401	1	0.3%	87	300	2
DEVENDERRAO, T.	P	03060	7	9.6%	37	73	21

684. This information allowed the RICO Diversion Defendants to track and identify instances of, overprescribing.⁴⁸⁵ In fact, one of the Data Venders' experts testified that a manufacturer of "narcotic analgesics" used the Data Venders' information to track, identify, report and halt suspicious orders of controlled substances.⁴⁸⁶

⁴⁸⁵ See *Sorrell v. IMS Health Inc.*, 2011 WL 1449043, *37-38 (March 24, 2011) (arguing that data had been used to "identify overuse of antibiotics in children," and "whether there is a wide use of anthrax prophylactic medicines after the scares happened in 2001."). The Data Vender Respondents also cited evidence from the trial court proving that "because analysis of PI data makes it possible to 'identify overuse of a pharmaceutical in specific conditions, the government employs the data to monitor usage of controlled substances.'" *Id.*

⁴⁸⁶ *Id.* at *38. Eugene "Mick" Kolassa testified as an expert on behalf of the Data Vender stating that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an

1 [455] Q. Besides marketing and promotion, are
2 there any other uses for prescriber-identifiable data?

3 A. There's a number of other uses.

4 Q. And what are those?

5 A. The one that I was most impressed with
6 was a firm that used it to identify – a firm that
7 sells narcotic analgesics was able to use prescriber-
8 identifiable information to identify physicians that
9 seemed to be prescribing an inordinately high num-
10 ber of prescriptions for their product and they would
11 use that to notify the DEA and other authorities of
12 potential problems.

13
14 685. The RICO Diversion Defendants were, therefore, collectively aware
15 of the suspicious orders that flowed daily from their manufacturing and distribution
16 facilities.

17 686. The RICO Diversion Defendants refused to identify, investigate and
18 report suspicious orders to the DEA when they became aware of the same despite
19 their actual knowledge of drug diversion rings. The RICO Diversion Defendants
20 refused to identify suspicious orders and diverted drugs despite the DEA issuing
21 final decisions against the Distributor Defendants in 178 registrant actions between
22 2008 and 2012⁴⁸⁷ and 117 recommended decision in registrant actions from The
23 Office of Administrative Law Judges. These numbers include seventy-six (76)

24
25
26 inordinately high number of prescriptions for their product.” *Id*; see also Joint
27 Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

28 ⁴⁸⁷ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of
Justice, *The Drug Enforcement Administration’s Adjudication of Registrant
Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

1 actions involving orders to show cause and forty-one (41) actions involving
 2 immediate suspension orders – all for failure to report suspicious orders.⁴⁸⁸

3 687. Defendants’ scheme had a decision-making structure driven by the
 4 Manufacturer Defendants and corroborated by the Distributor Defendants. The
 5 Manufacturer Defendants worked together to control the State and Federal
 6 Government’s response to the manufacture and distribution of prescription opioids
 7 by increasing production quotas through a systematic refusal to maintain effective
 8 controls against diversion, and identify suspicious orders and report them to the
 9 DEA.

10 688. The RICO Diversion Defendants worked together to control the flow
 11 of information and influence state and federal governments and political candidates
 12 to pass legislation that was pro-opioid. The Manufacturer and Distributor
 13 Defendants did this through their participation in the PCF and HDA.

14 689. The RICO Diversion Defendants also worked together to ensure that
 15 the Aggregate Production Quotas, Individual Quotas and Procurement Quotas
 16 allowed by the DEA remained artificially high and ensured that suspicious orders
 17 were not reported to the DEA in order to ensure that the DEA had no basis for
 18 refusing to increase or decrease production quotas due to diversion. The RICO
 19 Diversion Defendants influenced the DEA production quotas in the following ways:

20 690. The scheme devised and implemented by the RICO Diversion
 21 Defendants amounted to a common course of conduct characterized by a refusal to
 22 maintain effective controls against diversion, and all designed and operated to
 23 ensure the continued unlawful sale of controlled substances.

24 **C. PATTERN OF RACKETEERING ACTIVITY.**

25 691. The RICO Diversion Defendants conducted and participated in the
 26 conduct of the Opioid Diversion Enterprise through a pattern of racketeering
 27

28 ⁴⁸⁸ Id.

activity as defined in 18 U.S.C. § 1961(1)(D), including ; the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States; and 18 U.S.C. 1961(1)(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343).

**1. The RICO Defendants Manufactured, Sold and/or Dealt
in Controlled Substances and Their Actions Constitute
Crimes Punishable as Felonies.**

692. The RICO Diversion Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

693. The RICO Diversion Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

694. Each of the RICO Diversion Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

1 695. The CSA and the Code of Federal Regulations, require the RICO
 2 Diversion Defendants to make reports to the DEA of any suspicious orders
 3 identified through the design and operation of their system to disclose suspicious
 4 orders. The failure to make reports as required by the CSA and Code of Federal
 5 Regulations amounts to a criminal violation of the statute.

6 696. The RICO Diversion Defendants knowingly and intentionally
 7 furnished false or fraudulent information in their reports to the DEA about
 8 suspicious orders, and/or omitted material information from reports, records and
 9 other document required to be filed with the DEA including the Manufacturer
 10 Defendants' applications for production quotas. Specifically, the RICO Diversion
 11 Defendants were aware of suspicious orders of prescription opioids and the
 12 diversion of their prescription opioids into the illicit market, and failed to report this
 13 information to the DEA in their mandatory reports and their applications for
 14 production quotas.

15 697. Upon information and belief, the foregoing examples reflect the RICO
 16 Diversion Defendants' pattern and practice of willfully and intentionally omitting
 17 information from their mandatory reports to the DEA as required by 21 C.F.R. §
 18 1301.74. The sheer volume of enforcement actions available in the public record
 19 against the Distributor Defendants supports this conclusion.⁴⁸⁹ For example:

20 698. On April 24, 2007, the DEA issued an *Order to Show Cause and*
 21 *Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida
 22 distribution center ("Orlando Facility") alleging failure to maintain effective
 23 controls against diversion of controlled substances. On June 22, 2007,
 24 AmerisourceBergen entered into a settlement that resulted in the suspension of its
 25 DEA registration.

26
 27
 28 ⁴⁸⁹ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of
 Justice, *The Drug Enforcement Administration's Adjudication of Registrant*
Actions 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

1 699. On November 28, 2007, the DEA issued an *Order to Show Cause and*
2 *Immediate Suspension Order* against the Cardinal Health Auburn, Washington
3 Distribution Center (“Auburn Facility”) for failure to maintain effective controls
4 against diversion of hydrocodone.

5 700. On December 5, 2007, the DEA issued an *Order to Show Cause and*
6 *Immediate Suspension Order* against the Cardinal Health Lakeland, Florida
7 Distribution Center (“Lakeland Facility”) for failure to maintain effective controls
8 against diversion of hydrocodone.

9 701. On December 7, 2007, the DEA issued an *Order to Show Cause and*
10 *Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey
11 Distribution Center (“Swedesboro Facility”) for failure to maintain effective
12 controls against diversion of hydrocodone.

13 702. On January 30, 2008, the DEA issued an *Order to Show Cause and*
14 *Immediate Suspension Order* against the Cardinal Health Stafford, Texas
15 Distribution Center (“Stafford Facility”) for failure to maintain effective controls
16 against diversion of hydrocodone.

17 703. On May 2, 2008, McKesson Corporation entered into an
18 *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA which
19 provided that McKesson would “maintain a compliance program designed to detect
20 and prevent the diversion of controlled substances, inform DEA of suspicious
21 orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established
22 by its Controlled Substance Monitoring Program.”

23 704. On September 30, 2008, Cardinal Health entered into a *Settlement and*
24 *Release Agreement and Administrative Memorandum of Agreement* with the DEA
25 related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford
26 Facility. The document also referenced allegations by the DEA that Cardinal failed
27 to maintain effective controls against the diversion of controlled substances at its
28 distribution facilities located in McDonough, Georgia (“McDonough Facility”),

1 Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver
2 Facility”).

3 705. On February 2, 2012, the DEA issued an *Order to Show Cause and*
4 *Immediate Suspension Order* against the Cardinal Health Lakeland, Florida
5 Distribution Center (“Lakeland Facility”) for failure to maintain effective controls
6 against diversion of oxycodone.

7 706. On May, 14, 2012, Cardinal Health entered into an Administrative
8 Memorandum of Agreement with the DEA in which, among other things, Cardinal
9 Health “admits that its due diligence efforts for some pharmacy customers and its
10 compliance with the 2008 MOA, in certain respects, were inadequate.”

11 707. Thereafter, on December 23, 2016, Cardinal Health agreed to pay a
12 \$44 million fine to the DEA to resolve the civil penalty portion of the administrative
13 action taken against its Lakeland, Florida Distribution Center.

14 708. On January 5, 2017, McKesson Corporation entered into an
15 *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a
16 \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to
17 identify and report suspicious orders at its facilities in Aurora CO, Aurora IL,
18 Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI,
19 Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West
20 Sacramento CA.

1 709. In its Administrative Memorandum Agreement, McKesson
2 acknowledged its wrongdoing and failure to comply with the obligations imposed
3 by the CSA:

4 2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and
5 December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent
6 letters to every entity in the United States that was registered with DEA to manufacture or
7 distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters
8 contained, among other things, guidance for the identification and reporting of suspicious orders
9 to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times
10 during the period from January 1, 2009 up through and including the Effective Date of this
11 Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders
12 placed by certain pharmacies which should have been detected by McKesson as suspicious based
13 on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. §
14 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from
15 occurring in the future, including the measures delineated in the Compliance Addendum.

16 On or about May 2, 2008, DEA and McKesson entered into an Administrative
17 Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things,
18 that McKesson maintain a compliance program designed to detect and prevent the diversion of
19 controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b),
20 and follow procedures established by its Controlled Substance Monitoring Program ("CSMP").
21 McKesson acknowledges that, at various times during the Covered Time Period, it did not
22 identify or report to DEA certain orders placed by certain pharmacies, which should have been
23 detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth
24 in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the
25 future, including the measures delineated in the Compliance Addendum.

26 710. On April 23, 2015, McKesson filed a Form-8-K announcing a
27 settlement with the DEA and DOJ wherein it admitted to violating the CSA and
28 agreed to pay \$150 million and have some of its DEA registrations suspended on a
staggered basis.

 711. In 2016, the Los Angeles Times reported that Purdue was aware of a
pill mill operating out of Los Angeles yet failed to alert the DEA. The LA Times
uncovered that Purdue began tracking a surge in prescriptions in Los Angeles,
including one prescriber in particular. Documents published by the L.A. Times
reveal that a Purdue sales manager spoke with company officials, asking:

 712. Purdue was clearly aware of diversion. As a registrant, Purdue has the
same obligation to report suspicious orders as a wholesale distributor. Although
Purdue claimed that it was considering making a report to the DEA, it shirked its

1 responsibility, claimed that it was the wholesaler's responsibility and then reserved
2 the right to make the report:

3 713. Despite its knowledge of obvious diversion, "Purdue did not shut off
4 the supply of highly addictive OxyContin and did not tell authorities what it knew
5 about [a pill mill] until several years later when the clinic was out of business and
6 its leaders indicted. By that time, 1.1 million pills had spilled into the hands of
7 Armenian mobsters, the Crips gang and other criminals."

8 714. Finally, Mallinckrodt was recently the subject of a DEA and Senate
9 investigation for its opioid practices. Specifically, in 2011, the DEA targeted
10 Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as
11 500 million of its pills ended up in Florida between 2008 and 2012. After six years
12 of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million
13 fine. Federal prosecutors summarized the case by saying that Mallinckrodt's
14 response was that everyone knew what was going on in Florida but they had no duty
15 to report it.

16 715. These actions against the Distributor Defendants confirm that the
17 Distributor Defendants knew they had a duty to maintain effective controls against
18 diversion, design and operate a system to disclose suspicious orders, and to report
19 suspicious orders to the DEA. These actions also demonstrate, on information and
20 belief, that the Manufacturer Defendants were aware of the enforcement against
21 their Distributors and the diversion of the prescription opioids and a corresponding
22 duty to report suspicious orders.

23 716. The pattern of racketeering activity alleged herein is continuing as of
24 the date of this Complaint and, upon information and belief, will continue into the
25 future unless enjoined by this Court.

26 717. Many of the precise dates of the RICO Diversion Defendants' criminal
27 actions at issue herein were hidden and cannot be alleged without access to their
28 books and records. Indeed, an essential part of the successful operation of the

1 Opioid Diversion Enterprise depended upon the secrecy of the participants in that
2 enterprise.

3 718. Each instance of racketeering activity alleged herein was related, had
4 similar purposes, involved the same or similar participants and methods of
5 commission, and had similar results affecting similar victims, Plaintiffs'
6 Community and the County. Defendants calculated and intentionally crafted the
7 diversion scheme to increase and maintain profits from unlawful sales of opioids,
8 without regard to the effect such behavior would have on this jurisdiction, its
9 citizens or the County. The Defendants were aware that the County and the citizens
10 of this jurisdiction rely on the Defendants to maintain a closed system of
11 manufacturing and distribution to protect against the non-medical diversion and use
12 of their dangerously addictive opioid drugs.

13 719. By intentionally refusing to report and halt suspicious orders of their
14 prescription opioids, Defendants engaged in a fraudulent scheme and unlawful
15 course of conduct constituting a pattern of racketeering activity.

16 720. The RICO Diversion Defendants' predicate acts and pattern of
17 racketeering activity were a substantial and foreseeable cause of the County's injury
18 and the relationship between the RICO Diversion Defendants' conduct and the
19 County's injury are logical and not speculative. It was foreseeable to the RICO
20 Diversion Defendants that when they refused to identify, report and halt suspicious
21 orders as required by the CSA and Code of Federal Regulations, it would allow the
22 wide-spread diversion of prescriptions opioids into the illicit market and create an
23 opioid-addiction epidemic that logically, substantially, and foreseeably harmed the
24 County.

25 721. The RICO Diversion Defendants' predicate acts and pattern of
26 racketeering activity were a substantial and foreseeable cause of the County's injury
27 and the relationship between the RICO Diversion Defendants' conduct and the
28 County's injury is logical and not speculative. It was foreseeable to the RICO

1 Diversion Defendants that when they fraudulently marketed highly-addictive and
2 dangerous drugs, that were approved for very limited and specific uses by the FDA,
3 as non-addictive and safe for off-label uses such as moderate pain, non-cancer pain,
4 and long-term chronic pain, that the RICO Diversion Defendants would create an
5 opioid-addiction epidemic that logically, substantially and foreseeably harmed the
6 County.

7 722. The last racketeering incident occurred within five years of the
8 commission of a prior incident of racketeering.

9 **2. The RICO Diversion Defendants Engaged in Mail and**
10 **Wire Fraud.**

11 723. The RICO Diversion Defendants carried out, or attempted to carry out,
12 a scheme to defraud federal and state regulators, and the American public by
13 knowingly conducting or participating in the conduct of the Opioid Diversion
14 Enterprise through a pattern of racketeering activity within the meaning of 18
15 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of
16 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

17 724. The RICO Diversion Defendants committed, conspired to commit,
18 and/or aided and abetted in the commission of at least two predicate acts of
19 racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past
20 ten years. The multiple acts of racketeering activity that the RICO Diversion
21 Defendants committed, or aided and abetted in the commission of, were related to
22 each other, posed a threat of continued racketeering activity, and therefore
23 constitute a “pattern of racketeering activity.” The racketeering activity was made
24 possible by the RICO Diversion Defendants’ regular use of the facilities, services,
25 distribution channels, and employees of the Opioid Diversion Enterprise. The RICO
26 Diversion Defendants participated in the scheme to defraud by using mail,
27 telephone and the Internet to transmit mailings and wires in interstate or foreign
28 commerce.

1 725. The RICO Diversion Defendants used, directed the use of, and/or
2 caused to be used, thousands of interstate mail and wire communications in service
3 of their scheme through virtually uniform misrepresentations, concealments and
4 material omissions regarding their compliance with their mandatory reporting
5 requirements and the actions necessary to carry out their unlawful goal of selling
6 prescription opioids without reporting suspicious orders or the diversion of opioids
7 into the illicit market.

8 726. In devising and executing the illegal scheme, the RICO Diversion
9 Defendants devised and knowingly carried out a material scheme and/or artifice to
10 defraud by means of materially false or fraudulent pretenses, representations,
11 promises, or omissions of material facts. For the purpose of executing the illegal
12 scheme, the RICO Diversion Defendants committed these racketeering acts, which
13 number in the thousands, intentionally and knowingly with the specific intent to
14 advance the illegal scheme.

15 727. The RICO Diversion Defendants' predicate acts of racketeering (18
16 U.S.C. § 1961(1)) include, but are not limited to:

17 a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending
18 or receiving, or by causing to be sent and/or received, materials via U.S.
19 mail or commercial interstate carriers for the purpose of executing the
20 unlawful scheme to design, manufacture, market, and sell the prescription
21 opioids by means of false pretenses, misrepresentations, promises, and
22 omissions.

23 b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by
24 transmitting and/or receiving, or by causing to be transmitted and/or
25 received, materials by wire for the purpose of executing the unlawful
26 scheme to design, manufacture, market, and sell the prescription opioids
27 by means of false pretenses, misrepresentations, promises, and omissions.
28

1 728. The RICO Diversion Defendants' use of the mail and wires includes,
2 but is not limited to, the transmission, delivery, or shipment of the following by the
3 Manufacturers, Distributors, or third parties that were foreseeably caused to be sent
4 as a result of the RICO Diversion Defendants' illegal scheme, including but not
5 limited to:

- 6 a. The prescription opioids themselves;
- 7 b. Documents and communications that supported and/or facilitated the
8 Defendants' request for higher aggregate production quotas, individual
9 production quotas, and procurement quotas;
- 10 c. Documents and communications that facilitated the manufacture,
11 purchase and sale of prescription opioids;
- 12 d. Defendants' DEA registrations;
- 13 e. Documents and communications that supported and/or facilitated
14 Defendants' DEA registrations;
- 15 f. Defendants' records and reports that were required to be submitted to the
16 DEA pursuant to 21 U.S.C. § 827;
- 17 g. Documents and communications related to the Defendants' mandatory
18 DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- 19 h. Documents intended to facilitate the manufacture and distribution of
20 Defendants' prescription opioids, including bills of lading, invoices,
21 shipping records, reports and correspondence;
- 22 i. Documents for processing and receiving payment for prescription
23 opioids;
- 24 j. Payments from the Distributors to the Manufacturers;
- 25 k. Rebates and chargebacks from the Manufacturers to the Distributors;
- 26 l. Payments to Defendants' lobbyists through the PCF;
- 27 m. Payments to Defendants' trade organizations, like the HDA, for
28 memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

729. On information and belief, the RICO Diversion Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic oxycontin	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. (wholly-owned subsidiary of Endo)	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt PLC, (2) Mallinckrodt LLC (wholly-owned subsidiary of Mallinckrodt PLC)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
Allergan	(1) Allergan Plc, (2) Actavis LLC, (3) Actavis Pharma, Inc., (4) Actavis Plc, (5) Actavis, Inc., (6) Watson Pharmaceuticals, Inc., (7) Watson Pharma, Inc.	Kadian	Morphine Sulfate	Schedule II
		Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

730. Each of the RICO Diversion Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

731. The RICO Diversion Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Diversion Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

732. At the same time, the RICO Diversion Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

733. Upon information and belief, the RICO Diversion Defendants utilized the internet and other electronic resources to exchange communications, to

1 exchange information regarding prescription opioid sales, and to transmit payments
2 and rebates/chargebacks.

3 734. The RICO Diversion Defendants also communicated by U.S. Mail, by
4 interstate facsimile, and by interstate electronic mail with each other and with
5 various other affiliates, regional offices, regulators, distributors, and other third-
6 party entities in furtherance of the scheme.

7 735. The mail and wire transmissions described herein were made in
8 furtherance of Defendants' scheme and common course of conduct to deceive
9 regulators, the public and The County that Defendants were complying with their
10 state and federal obligations to identify and report suspicious orders of prescription
11 opioids all while Defendants were knowingly allowing millions of doses of
12 prescription opioids to divert into the illicit drug market. The RICO Diversion
13 Defendants' scheme and common course of conduct was to increase or maintain
14 high production quotas for their prescription opioids from which they could profit.

15 736. Many of the precise dates of the fraudulent uses of the U.S. mail and
16 interstate wire facilities have been deliberately hidden by Defendants and cannot be
17 alleged without access to Defendants' books and records. However, Plaintiffs have
18 described the types of, and in some instances, occasions on which the predicate acts
19 of mail and/or wire fraud occurred. They include thousands of communications to
20 perpetuate and maintain the scheme, including the things and documents described
21 in the preceding paragraphs.

22 737. The RICO Diversion Defendants did not undertake the practices
23 described herein in isolation, but as part of a common scheme. Various other
24 persons, firms, and corporations, including third-party entities and individuals not
25 named as defendants in this Complaint, may have contributed to and/or participated
26 in the scheme with the RICO Diversion Defendants in these offenses and have
27 performed acts in furtherance of the scheme to increase revenues, increase market
28 share, and /or minimize the losses for the RICO Diversion Defendants.

1 738. The RICO Diversion Defendants aided and abetted others in the
2 violations of the above laws, thereby rendering them indictable as principals in the
3 18 U.S.C. §§ 1341 and 1343 offenses.

4 739. The RICO Diversion Defendants hid from the general public and
5 suppressed and/or ignored warnings from third parties, whistleblowers and
6 governmental entities about the reality of the suspicious orders that the RICO
7 Diversion Defendants were filling on a daily basis – leading to the diversion of
8 hundreds of millions of doses of prescriptions opioids into the illicit market.

9 740. The RICO Diversion Defendants, with knowledge and intent, agreed
10 to the overall objective of their fraudulent scheme and participated in the common
11 course of conduct to commit acts of fraud and indecency in manufacturing and
12 distributing prescription opioids.

13 741. Indeed, for the Defendants' fraudulent scheme to work, each of the
14 Defendants had to agree to implement similar tactics regarding manufacturing
15 prescription opioids and refusing to report suspicious orders.

16 742. As described herein, the RICO Diversion Defendants engaged in a
17 pattern of related and continuous predicate acts for years. The predicate acts
18 constituted a variety of unlawful activities, each conducted with the common
19 purpose of obtaining significant monies and revenues from the sale of their highly
20 addictive and dangerous drugs. The predicate acts also had the same or similar
21 results, participants, victims, and methods of commission. The predicate acts were
22 related and not isolated events.

23 743. The predicate acts all had the purpose of creating the opioid epidemic
24 that substantially injured the County's business and property, while simultaneously
25 generating billion-dollar revenue and profits for the RICO Diversion Defendants.
26 The predicate acts were committed or caused to be committed by the RICO
27 Diversion Defendants through their participation in the Opioid Diversion Enterprise
28 and in furtherance of its fraudulent scheme.

1 744. The pattern of racketeering activity alleged herein and the Opioid
2 Diversion Enterprise are separate and distinct from each other. Likewise,
3 Defendants are distinct from the enterprise.

4 745. The pattern of racketeering activity alleged herein is continuing as of
5 the date of this Complaint and, upon information and belief, will continue into the
6 future unless enjoined by this Court.

7 746. Many of the precise dates of the RICO Diversion Defendants' criminal
8 actions at issue here have been hidden by Defendants and cannot be alleged without
9 access to Defendants' books and records. Indeed, an essential part of the successful
10 operation of the Opioid Diversion Enterprise alleged herein depended upon secrecy.

11 747. Each instance of racketeering activity alleged herein was related, had
12 similar purposes, involved the same or similar participants and methods of
13 commission, and had similar results affecting similar victims, including Plaintiffs'
14 Community and the County. Defendants calculated and intentionally crafted the
15 Opioid Diversion Enterprise and their scheme to increase and maintain their
16 increased profits, without regard to the effect such behavior would have on
17 Plaintiffs' Community, its citizens or the County. In designing and implementing
18 the scheme, at all times Defendants were cognizant of the fact that those in the
19 manufacturing and distribution chain rely on the integrity of the pharmaceutical
20 companies and ostensibly neutral third parties to provide objective and reliable
21 information regarding Defendants' products and their manufacture and distribution
22 of those products. The Defendants were also aware that The County and the citizens
23 of this jurisdiction rely on the Defendants to maintain a closed system and to protect
24 against the non-medical diversion and use of their dangerously addictive opioid
25 drugs.

26 748. By intentionally refusing to report and halt suspicious orders of their
27 prescription opioids, Defendants engaged in a fraudulent scheme and unlawful
28 course of conduct constituting a pattern of racketeering activity.

1 749. It was foreseeable to Defendants that The County would be harmed
 2 when they refused to report and halt suspicious orders, because their violation of
 3 the duties imposed by the CSA and Code of Federal Regulations allowed the
 4 widespread diversion of prescription opioids out of appropriate medical channels
 5 and into the illicit drug market – causing the opioid epidemic that the CSA intended
 6 to prevent.

7 750. The last racketeering incident occurred within five years of the
 8 commission of a prior incident of racketeering.

9 **D. DAMAGES.**

10 **1. Impact of the Opioid Diversion Enterprise.**

11 751. California has been especially ravaged by the national opioid crisis.

12 752. More people die each year from drug overdoses in California than in
 13 any other state.⁴⁹⁰ The State's death rate has continued to climb, increasing by 30
 14 percent from 1999 to 2015, according to the Center for Disease Control (CDC).⁴⁹¹

15 753. In 2016, 1,925 Californians died due to prescription opioids.⁴⁹² This
 16 number is on par with other recent years: in 2015, 1,966 deaths in California were
 17 due just to prescription opioids (not including heroin); in 2014 that number was
 18 even higher at 2,024 prescription opioid deaths; and in 2013, 1,934 Californians
 19 died from a prescription opioid overdose.⁴⁹³

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25 ⁴⁹⁰ Davis, *supra*.

26 ⁴⁹¹ Karlamangla, *supra*.

27 ⁴⁹² Davis, *supra*.

28 ⁴⁹³ California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, available at https://pdop.shinyapps.io/ODdash_v1/ (last visited March 2, 2018).

754. Of the 1,925 opioid-related deaths in California in 2016, fentanyl was a factor in at least 234 of them.⁴⁹⁴ This is an increase of 47 percent for 2016.⁴⁹⁵ Heroin-related deaths have risen by 67 percent in California since 2006.⁴⁹⁶

755. The high number of deaths are due in part to the extraordinary number of opioids prescribed in the State. Over 23.6 million prescriptions for opioids were written in California in just 2016.⁴⁹⁷

756. The California Department of Public Health tracks the number of reported hospitalizations and emergency department visits due to prescription opioids.⁴⁹⁸ In 2015, the last year for which information is currently available, California had 3,935 emergency department visits and 4,095 hospitalizations related to prescription opioid overdoses (excluding heroin).⁴⁹⁹ The numbers were even higher in 2014, when 4,106 people visited the emergency department and 4,482 people were hospitalized due to prescription opioid abuse.⁵⁰⁰ In 2013, there were 3,964 emergency department visits and 4,344 hospitalizations for prescription opioid overdoses.⁵⁰¹ When emergency visits and hospitalizations include heroin, the numbers are even higher.⁵⁰²

⁴⁹⁴ Davis, *supra*.

⁴⁹⁵ Karlamangla, *supra*.

⁴⁹⁶ California Department of Public Health, *State of California Strategies to Address Prescription Drug (Opioid) Misuse, Abuse, and Overdose Epidemic in California* at 3 (June 2016), available at <https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/CDPH%20Document%20Library/Prescription%20Drug%20Overdose%20Program/CAOpioidPreventionStrategies4.17.pdf> (last visited March 2, 2018).

⁴⁹⁷ California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, *supra*.

498 *Id.*

499 *Id.*

500 *Id.*

501 *Id.*

502 *Id.*

1 757. NAS has increased dramatically in California, with the rate of infants
 2 born with NAS more than tripling from 2008 to 2013.⁵⁰³ While the number of
 3 affected newborns rose from 1,862 in 2008 to 3,007 in 2014, that number jumped
 4 by another 21 percent in 2015.⁵⁰⁴ This is despite a steady decline in the overall
 5 number of birth in California during that same time.⁵⁰⁵

6 758. Reports from California's Office of Statewide Health Planning, which
 7 collects data from licensed health care facilities, have shown a 95 percent increase
 8 between 2008 and 2015 of newborns affected by drugs transmitted via placenta or
 9 breast milk.⁵⁰⁶

10 759. The opioid epidemic has also had an impact on crime in California.
 11 Pharmacy robberies have gone up by 163 percent in California over the last two
 12 years, according to the DEA. The DEA recorded 90 incidents in 2015, 154 in 2016
 13 and, through mid-November of 2017, that number had climbed to 237.⁵⁰⁷ Most
 14 perpetrators were after prescription opioids.⁵⁰⁸ In addition, fentanyl seizures at
 15 California ports increased 266 percent in fiscal year 2017.⁵⁰⁹

16 760. The opioid epidemic is particularly devastating in Plaintiffs'
 17 Community.

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 21 ⁵⁰³ California Child Welfare Co-Investment Partnership, *supra* at 5.

22 ⁵⁰⁴ Clark, *supra*.

23 ⁵⁰⁵ *Id.*

24 ⁵⁰⁶ California Child Welfare Co-Investment Partnership, *supra*.

25 ⁵⁰⁷ Ed Fletcher, "What's behind the spike in drug store robberies?" *The Sacramento Bee*, Dec. 8, 2017 (available at
 26 <http://www.sacbee.com/news/local/crime/article188636384.html> (last visited
 March 2, 2018)).

27 ⁵⁰⁸ *Id.*

28 ⁵⁰⁹ United State Department of Justice, The United States Attorney's Office,
 Southern District of California, *U.S. Attorney Appoints Opioid Coordinators* (Feb.
 8, 2018) available at [https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-](https://www.justice.gov/usao-sdca/pr/us-attorney-appoints-opioid-coordinators)
 opioid-coordinators (last visited March 2, 2018).

1 761. In 2016, the County had an opioid overdose death rate of 8.1 per
2 100,000 people.⁵¹⁰ In 2015, the County's opioid overdose death rate was in the
3 second highest quartile in the State.⁵¹¹

4 762. In 2016, an estimated 5.9 percent of the population aged 12 and up in
5 Yuba County misused opioids – that's over 4,000 people – and over one percent
6 (728 people) had an opioid use disorder.⁵¹²

7 763. From 2012-2014, the County suffered 22 deaths due to drug overdoses
8 for a drug overdose mortality rate of 10 deaths per 100,000 residents.⁵¹³

9 764. The CDC has tracked prescription rates per county in the United
10 States, identifying the geographic “hotspots” for rates of opioid prescriptions.⁵¹⁴
11 The CDC has calculated the geographic distribution at county levels of opioid
12 prescriptions dispensed per 100 persons,⁵¹⁵ revealing that Yuba County has been a
13 consistent hotspot over at least the past decade.

14 765. The CDC's statistics prove that the opioid prescription rates in Yuba
15 County have exceeded any legitimate medical, scientific, or industrial purpose. The
16 overall opioid prescribing rate in 2016 was 66.5 prescriptions per 100 people and
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19 ⁵¹⁰ California Department of Public Health, *California Opioid Overdose*
20 *Surveillance Dashboard*, available at https://pdop.shinyapps.io/ODdash_v1/ (last
21 visited April 20, 2018) (Yuba County specific page).

22 ⁵¹¹ Public Health Institute, *Tackling An Epidemic: An Assessment of the California*
23 *Opioid Safety Coalitions Network*, at p. 11, available at
24 [https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27tt](https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27tt dpzxmbclj7cxq99alz.pdf)
25 [dpzxmbclj7cxq99alz.pdf](https://www.phi.org/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27tt dpzxmbclj7cxq99alz.pdf) (last visited April 20, 2018).

26 ⁵¹² Lisa Clemans-Cope, Marni Epstein, and Doug Wissoker, “County-Level
27 Estimates of Opioid Use Disorder and Treatment Needs in California,” *The Urban*
28 *Institute*, March 19, 2018, available at
<https://www.urban.org/sites/default/files/yuba.pdf> (last visited April 20, 2018).

⁵¹³ County Health Rankings & Roadmaps, Drug overdose deaths, available at
[http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/dat](http://www.countyhealthrankings.org/app/california/2016/measure/factors/138/data)
a (last visited April 20, 2018).

⁵¹⁴ U.S. Prescribing Rate Maps, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
2017).

⁵¹⁵ *Id.*

1 44.8 in California.⁵¹⁶ However, in Yuba County, California, the 2016 prescription
 2 rate was 83.2 per 100 people.⁵¹⁷ This is down from the 2015 prescribing rate for
 3 Yuba County which was 92.0 per 100 people.⁵¹⁸

4 766. Unfortunately, the 2015 and 2016 high rates of opioid prescriptions
 5 were not an aberration for Yuba County. Consistently, the opioid prescribing rates
 6 in Yuba County have been among the highest in the state, significantly greater than
 7 the national and state averages, and often more than one prescription per person
 8 living in the County. Compared to a national average of 75.6 opioid prescriptions
 9 per 100 people in 2014⁵¹⁹ and 52.7 in California,⁵²⁰ the Yuba County opioid
 10 prescription rate was 96.2 per 100 people.⁵²¹ In 2013, the national average was 78.1
 11 opioid prescriptions per 100 people,⁵²² but the opioid prescription rate in Yuba
 12 County was 105.5 per 100 people – more than one prescription for every man,

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 16 ⁵¹⁶ *Id.* See also U.S. State Prescribing Rates, 2016, available at
 17 <https://www.cdc.gov/drugoverdose/maps/rxstate2016.html> (last visited April 18,
 2018).

18 ⁵¹⁷ U.S. County Prescribing Rates, 2016, (reporting for “Yuba, CA” here and
 19 below) CDC available at
 20 <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html> (last visited April 18,
 2018).

21 ⁵¹⁸ U.S. County Prescribing Rates, 2015, CDC, available at
 22 <https://www.cdc.gov/drugoverdose/maps/rxcounty2015.html> (last visited April 18,
 2018).

23 ⁵¹⁹ U.S. Prescribing Rate Maps, CDC, available at
 24 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

25 ⁵²⁰ U.S. State Prescribing Rates, 2014, CDC, available at
 26 <https://www.cdc.gov/drugoverdose/maps/rxstate2014.html> (last visited Dec. 11,
 2017).

27 ⁵²¹ U.S. County Prescribing Rates, 2014, CDC, available at
 28 <https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html> (last visited April 18,
 2018).

⁵²² U.S. Prescribing Rate Maps, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

1 woman and child in Yuba County.⁵²³ Compared to a national average of 81.3 opioid
 2 prescriptions per 100 people in 2012,⁵²⁴ the opioid prescription rate in Yuba County
 3 was 108 per 100 people that year.⁵²⁵ In 2011, the national average was 80.9 opioid
 4 prescriptions per 100 people,⁵²⁶ but the opioid prescription rate in Yuba County was
 5 108.8 per 100 people.⁵²⁷ Compared to a national average of 81.2 opioid
 6 prescriptions per 100 people in 2010,⁵²⁸ the Yuba County opioid prescription rate
 7 was 111.2 per 100 people – an all-time high for Yuba County.⁵²⁹ In 2009, the
 8 national average was 79.5 opioid prescriptions per 100 people,⁵³⁰ but the rate in
 9 Yuba County was 98.5.⁵³¹ Compared to a national average of 78.2 opioid

13 ⁵²³ U.S. County Prescribing Rates, 2013, CDC, available at
 14 <https://www.cdc.gov/drugoverdose/maps/rxcounty2013.html> (last visited April 18,
 2018).

15 ⁵²⁴ U.S. Prescribing Rate Maps, CDC, available at
 16 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

17 ⁵²⁵ U.S. County Prescribing Rates, 2012, CDC, available at
 18 <https://www.cdc.gov/drugoverdose/maps/rxcounty2012.html> (last visited April 18,
 2018).

19 ⁵²⁶ U.S. Prescribing Rate Maps, CDC, available at
 20 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

21 ⁵²⁷ U.S. County Prescribing Rates, 2011, CDC, available at
 22 <https://www.cdc.gov/drugoverdose/maps/rxcounty2011.html> (last visited April 18,
 2018).

23 ⁵²⁸ U.S. Prescribing Rate Maps, CDC, available at
 24 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

25 ⁵²⁹ U.S. County Prescribing Rates, 2010, CDC, available at
 26 <https://www.cdc.gov/drugoverdose/maps/rxcounty2010.html> (last visited April 18,
 2018).

27 ⁵³⁰ U.S. Prescribing Rate Maps, CDC, available at
 28 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

⁵³¹ U.S. County Prescribing Rates, 2009, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxcounty2009.html> (last visited April 18,
 2018).

1 prescriptions per 100 people in 2008⁵³² and 55.1 in California,⁵³³ the Yuba County
 2 rate was 84 per 100 people.⁵³⁴

3 **2. The Relief Sought.**

4 767. The RICO Diversion Defendants' violations of law and their pattern
 5 of racketeering activity directly and proximately caused the County injury in its
 6 business and property. The RICO Diversion Defendants' pattern of racketeering
 7 activity, including their refusal to identify, report and halt suspicious orders of
 8 controlled substances, logically, substantially and foreseeably cause an opioid
 9 epidemic. The County was injured by the RICO Diversion Defendants' pattern of
 10 racketeering activity and the opioid epidemic that they created.

11 768. As the County alleges, the RICO Diversion Defendants knew that the
 12 opioids they manufactured and supplied were unsuited to treatment of long-term,
 13 chronic, non-acute, and non-cancer pain, or for any other use not approved by the
 14 FDA, and knew that opioids were highly addictive and subject to abuse.⁵³⁵
 15 Nevertheless, the RICO Diversion Defendants engaged in a scheme of deception,
 16 that utilized the mail and wires as part of their fraud, in order to increase sales of
 17 their opioid products by refusing to identify, report suspicious orders of prescription
 18 opioids that they knew were highly addictive, subject to abuse, and were actually
 19 being diverted into the illegal market.⁵³⁶

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 22 ⁵³² U.S. Prescribing Rate Maps, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last visited Oct. 30,
 2017).

23 ⁵³³ U.S. State Prescribing Rates, 2008, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxstate2008.html> (last visited Dec. 11,
 2017).

25 ⁵³⁴ U.S. County Prescribing Rates, 2008, CDC, available at
<https://www.cdc.gov/drugoverdose/maps/rxcounty2008.html> (last visited April 18,
 2018).

27 ⁵³⁵ *Traveler's Property Casualty Company of America v. Actavis, Inc.*, 22 Cal.
 Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

28 ⁵³⁶ *City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, *6 (W.D. Wash.
 Sept. 25, 2017).

1 769. Here, as the County alleges, the link of causation generally breaks
 2 down into three very short steps: (1) the RICO Diversion Defendants' affirmative
 3 action to continue supplying prescription opioids through legal channels with
 4 knowledge that they were being diverted into the illicit market; (2) an opioid
 5 epidemic in the form of criminal drug trafficking, misuse and abuse; and (3) injuries
 6 to the County.⁵³⁷ Although not as direct as a car accident or a slip-and-fall case,
 7 this causal chain is still a "direct sequence" and a logical, substantial and
 8 foreseeable cause of the County's injury.⁵³⁸

9 770. Specifically, the RICO Diversion Defendants' predicate acts and
 10 pattern of racketeering activity caused the opioid epidemic which has injured the
 11 County in the form of substantial losses of money and property that logically,
 12 directly and foreseeably arise from the opioid-addiction epidemic. The County's
 13 injuries, as alleged throughout this complaint, and expressly incorporated herein by
 14 reference, include:

- 15 a. Losses caused by purchasing and/or paying reimbursements for the RICO
 16 Defendants' prescription opioids, that The County would not have paid
 17 for or purchased but for the RICO Diversion Defendants' conduct;
- 18 b. Losses caused by the decrease in funding available for The County's
 19 public services for which funding was lost because it was diverted to other
 20 public services designed to address the opioid epidemic;
- 21 c. Costs for providing healthcare and medical care, additional therapeutic,
 22 and prescription drug purchases, and other treatments for patients
 23 suffering from opioid-related addiction or disease, including overdoses
 24 and deaths;

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 28 ⁵³⁷ *Id.*

⁵³⁸ *Id.*

- d. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
- e. Costs associated with providing police officers and others with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- f. Costs associated with emergency responses by police officers and others to opioid overdoses;
- g. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- h. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;
- i. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
- j. Costs associated with increased burden on the County’s judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- k. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- l. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs’ Community;

1 m. Losses caused by diminished property values in neighborhoods where the
2 opioid epidemic has taken root; and

3 n. Losses caused by diminished property values in the form of decreased
4 business investment and tax revenue.

5 771. The County's injuries were proximately caused by Defendants'
6 racketeering activities because they were the logical, substantial and foreseeable
7 cause of The County's injuries. But for the opioid-addiction epidemic created by
8 Defendants' conduct, The County would not have lost money or property.

9 772. The County's injuries were directly caused by the RICO Diversion
10 Defendants' pattern of racketeering activities.

11 773. The County is most directly harmed and there is no other Plaintiff
12 better suited to seek a remedy for the economic harms at issue here.

13 774. Plaintiff seeks all legal and equitable relief as allowed by law,
14 including *inter alia* actual damages, treble damages, equitable relief, forfeiture as
15 deemed proper by the Court, attorney's fees and all costs and expenses of suit and
16 pre- and post-judgment interest

17 **COUNT V**

18 **FALSE ADVERTISING**

19 **Violations of California Business and Professions Code section 17500, et seq.**

20 **(Against All Defendants)**

21 775. Plaintiff, The People, incorporate by reference all other paragraphs of
22 this Complaint as if fully set forth here, and further alleges as follows.

23 776. This Count is brought by the People of the State. This Count is brought
24 pursuant to Sections 17535 and 17536 of the California Business and Professions
25 Code for injunctive relief, restitution and civil penalties.

26 777. Section 17500 of the California Business and Professions Code makes
27 it "unlawful for any person, . . . corporation . . . with intent directly or indirectly to
28 dispose of real or personal property . . . or to induce the public to enter into any

1 obligation relating thereto, to make or disseminate or cause to be made or
2 disseminated before the public in this state, . . . in any . . . manner or means whatever
3 . . . any statement, concerning that real or personal property . . . which is untrue or
4 misleading, and which is known, or which by the exercise of reasonable care should
5 be known, to be untrue or misleading.” Cal. Bus. & Prof. Code § 17500.

6 778. As described above in allegations expressly incorporated herein, at all
7 times relevant to this Complaint, Defendants directly and indirectly violated Section
8 17500 by making and disseminating untrue, false and misleading statements about,
9 *inter alia*, the use of opioids for chronic pain, about the risks of addiction related to
10 opioids, about the signs of addiction and how to reliably identify and safely
11 prescribe opioids to patients predisposed to addiction, and about their so-called
12 abuse-deterrent opioid formulations. Defendants also repeatedly failed to disclose
13 material facts about the risks of opioids.

14 779. The Manufacturer Defendants also made untrue, false, and misleading
15 statements that included, but were not limited to:

16 780. Claiming or implying that opioids would improve patients’ function
17 and quality of life;

18 781. Claiming that opioids should be used to treat chronic pain and that
19 there was a significant upside to long-term opioid use;

20 782. Mischaracterizing the risk of opioid addiction and abuse, including by
21 stating or implying the opioids were rarely addictive, that “steady state” and abuse-
22 resistant properties meant the drugs were less likely to be addictive or abused, and
23 that specific opioid drugs were less addictive or less likely to be abused than other
24 opioids;

25 783. Claiming or implying that addiction can be avoided or successfully
26 managed through the use of screening and other tools and exaggerating the
27 effectiveness of screening tools to prevent addiction;
28

1 784. Promoting the misleading concept of pseudoaddiction, thus concealing
2 the true risk of addiction, and advocating that the signs of addiction should be
3 treated with more opioids;

4 785. Mischaracterizing the difficulty of discontinuing opioid therapy,
5 including by mischaracterizing the prevalence and severity of withdrawal
6 symptoms, and claiming that opioid dependence and withdrawal are easily
7 managed;

8 786. Claiming of implying that increased doses of opioids pose no
9 significant additional risk;

10 787. Misleadingly depicting the safety profile of opioids prescribed by
11 minimizing their risks and adverse effects while emphasizing or exaggerating the
12 risks of competing products, including NSAIDs; and

13 788. In the case of Purdue, mischaracterizing OxyContin's onset of action
14 and duration of efficacy to imply that the drug provided a full 12 hours of pain
15 relief.

16 789. The Manufacturer Defendants made deceptive representations to the
17 public about the use of opioids to treat chronic non-cancer pain. Each Manufacturer
18 Defendant also omitted or concealed material facts and failed to correct prior
19 misrepresentations and omissions to the public about the risks and benefits of
20 opioids. Each Defendant's omissions rendered even their seemingly truthful
21 statements about opioids deceptive.

22 790. Defendants' conduct was likely to mislead or deceive The People and
23 Plaintiffs' Community, including Californians who purchased or covered or paid
24 for the purchase of opioids for chronic pain.

25 791. Each Manufacturer Defendant has conducted, and has continued to
26 conduct, a widespread marketing scheme designed to promote opioids and persuade
27 doctors and patients that opioids can and should be used for chronic pain, resulting
28 in opioid treatment for a far broader group of patients who are much more likely to

1 become addicted and suffer other adverse effects from the long-term use of opioids.
2 In connection with this scheme, each Manufacturer Defendant spent, and continues
3 to spend, millions of dollars on promotional activities and materials that falsely
4 deny or trivialize the risks of opioids while overstating the benefits of using them
5 for chronic pain. This conduct tends to mislead or deceive, and has misled and
6 deceived, The People and Plaintiffs' Community.

7 792. The Manufacturer Defendants have disseminated these common
8 messages to reverse the popular and medical understanding of opioids and risks of
9 opioid use. They disseminated these messages directly, through their sales
10 representatives, in speaker groups led by physicians the Manufacturer Defendants
11 recruited for their support of their marketing messages, and through unbranded
12 marketing and industry-funded front groups.

13 793. Pursuant to Section 17535 of the California Business and Professions
14 Code, The People request an order from this Court enjoining Defendants from any
15 further violations of the California False Advertising law, California Business and
16 Professions Code §§ 17500 *et seq.*

17 794. Pursuant to Section 17535 of the California Business and Professions
18 Code, the People request restitution of any money acquired by Defendants'
19 violations of the California False Advertising law, California Business and
20 Professions Code §§ 17500 *et seq.*

21 795. Pursuant to Section 17536 of the California Business and Professions
22 Code, The People request an order assessing a civil penalty of two thousand five
23 hundred dollars (\$2,500) against Defendants for each violation of the California
24 False Advertising law, California Business and Professions Code §§ 17500 *et seq.*
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COUNT VI

NEGLIGENT MISREPRESENTATION

(Against All Defendants)

796. Plaintiff, The County, incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

797. The County seeks economic damages which were the foreseeable result of the Defendants' intentional and/or unlawful actions and omissions.

798. California classifies negligent misrepresentation as a species of fraud or deceit for which economic losses are recoverable. *Kalitta Air, L.L.C. v. Cent. Texas Airborne Sys., Inc.*, 315 F. App'x 603, 607 (9th Cir. 2008) (citing *Bily v. Arthur Young & Co.*, 3 Cal. 4th 370, 11 Cal. Rptr. 2d 51, 834 P.2d 745, 768 (1992)).

799. The elements of negligent misrepresentation in California are that the defendant: (1) made a misrepresentation of a past or existing material fact, (2) without reasonable grounds for believing it to be true, (3) with the intent to induce another's reliance on the misrepresentation, (4) justifiable reliance on the misrepresentation, and (5) resulting damage. *Wells Fargo Bank, N.A. v. FSI, Fin. Sols., Inc.*, 196 Cal. App. 4th 1559, 1573, 127 Cal. Rptr. 3d 589, 600 (2011); *Fox v. Pollack*, 181 Cal. App. 3d 954, 962, 226 Cal. Rptr. 532, 536–37 (Ct. App. 1986). Negligent misrepresentation “encompasses ‘[t]he assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true.’” *Small v. Fritz Companies, Inc.*, 30 Cal. 4th 167, 173–74, 65 P.3d 1255, 1258 (2003) (citing Cal. Civ. Code § 1710(2)).

800. As described elsewhere in this Complaint in allegations expressly incorporated herein, Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiffs' Community and destinations from which they knew opioids were likely to be diverted into Plaintiffs' Community, in addition to other misrepresentations alleged and incorporated herein.

1 801. As described elsewhere in the Complaint in allegations expressly
2 incorporated herein, Manufacturer Defendants breached their duties to exercise due
3 care in the business of pharmaceutical manufacturers of dangerous opioids, which
4 are Schedule II Controlled Substances, by misrepresenting the nature of the drugs
5 and aggressively promoting them for chronic pain for which they knew the drug
6 were not safe or suitable.

7 802. The Manufacturer Defendants misrepresented and concealed the
8 addictive nature of prescription opioids and their lack of suitability for chronic pain,
9 in addition to other misrepresentations alleged and incorporated herein.

10 803. All Defendants breached their duties to prevent diversion and report
11 and halt suspicious orders, and they misrepresented their compliance with their
12 legal duties. Defendants knew or should have known that the representations they
13 were making were untrue because they did not have reasonable grounds for
14 believing their statements to be true.

15 804. Defendants made these false representations and concealed facts with
16 knowledge of the falsity of their representations, or without reasonable grounds for
17 believing them to be true, and did so with the intent of inducing reliance by The
18 County, Plaintiffs' Community, the public, and persons on whom The County
19 relied.

20 805. These false representations and concealments were reasonably
21 calculated to deceive The County, Plaintiffs' Community, and the physicians who
22 prescribed opioids for persons in Plaintiffs' Community, were made with the intent
23 of inducing reliance, and did in fact deceive these persons, The County, and
24 Plaintiffs' Community.

25 806. The County, Plaintiffs' Community, and the physicians who
26 prescribed opioids reasonably relied on these false representations and
27 concealments of material fact
28

1 807. The County justifiably relied on Defendants' representations and/or
2 concealments, both directly and indirectly. This reliance proximately caused The
3 County's injuries.

4 808. The causal connection between the Defendants' breaches of their
5 duties and misrepresentations and the ensuing harm was entirely foreseeable.

6 809. As described above in allegations expressly incorporated herein,
7 Defendants' breaches of duty and misrepresentations caused, bear a causal
8 connection with and/or proximately resulted in the damages sought herein.

9 810. The Defendants' breaches of their duties and misrepresentations were
10 the cause-in-fact of The County's injuries.

11 811. The risk of harm to The County and Plaintiffs' Community and the
12 harm caused should have been reasonably foreseen by Defendants. The Defendants'
13 conduct was substantial factor in causing The County's injuries.

14 812. The Defendants were selling dangerous drugs statutorily categorized
15 as posing a high potential for abuse and severe dependence. The Defendants
16 knowingly traded in drugs that presented a high degree of danger if prescribed
17 incorrectly or diverted to other than medical, scientific, or industrial channels.
18 However, the Defendants misrepresented what their duties were and their
19 compliance with their legal duties.

20 813. The Defendants failed to disclose the material facts that *inter alia* they
21 were not in compliance with laws and regulations requiring that they maintain a
22 system to prevent diversion, protect against addiction and severe harm, and
23 specifically monitor, investigate, report, and refuse suspicious orders. But for these
24 material factual omissions, the Defendants would not have been able to sell opioids.

25 814. As alleged herein, each Manufacturer Defendant wrongfully
26 represented that the opioid prescription medications they manufactured, marketed
27 and sold had characteristics, uses or benefits that they do not have. The
28 Manufacturer Defendants also wrongfully misrepresented that the opioids were safe

1 and effective when the Manufacturer Defendants knew, or should have known, such
2 representations were untrue, false and misleading.

3 815. Because of the dangerously addictive nature of these drugs, which the
4 Manufacturer Defendants concealed and misrepresented, they lacked medical value
5 and in fact caused addiction and overdose deaths.

6 816. The Manufacturer Defendants made deceptive representations about
7 the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant
8 also omitted or concealed material facts and failed to correct prior
9 misrepresentations and omissions about the risks and benefits of opioids. Each
10 Defendant's omissions rendered even their seemingly truthful statements about
11 opioids deceptive.

12 817. The Defendants' unlawful and/or intentional actions create a
13 rebuttable presumption of negligent misrepresentation under State law.

14 818. The County seeks economic losses (direct, incidental, or consequential
15 pecuniary losses) resulting from the Defendants' actions and omissions.

16 819. The County seeks all legal and equitable relief as allowed by law, other
17 than such damages disavowed herein, including *inter alia* injunctive relief,
18 restitution, disgorgement of profits, compensatory and punitive damages, and all
19 damages allowed by law to be paid by the Defendants, attorney fees and costs, and
20 pre- and post-judgment interest.

21 **COUNT VII**

22 **FRAUD AND FRAUDULENT MISREPRESENTATION**

23 **(Against All Defendants)**

24 820. Plaintiff, The County, incorporates by reference all other paragraphs
25 of this Complaint as if fully set forth here, and further alleges as follows.

26 821. In California, the tort of fraud or intentional misrepresentation has five
27 elements: "The elements of fraud, which gives rise to the tort action for deceit, are
28 (a) misrepresentation (false representation, concealment, or nondisclosure); (b)

1 knowledge of falsity (or ‘scienter’); (c) intent to defraud, i.e., to induce reliance; (d)
2 justifiable reliance; and (e) resulting damage.’” *Small v. Fritz Companies, Inc.*, 30
3 Cal. 4th 167, 173–74, 65 P.3d 1255, 1258 (2003) (citing *Lazar v. Superior Court*,
4 12 Cal. 4th 631, 638, 49 Cal. Rptr. 2d 377, 909 P.2d 981 (1996)).

5 822. Section 1709 of the California Civil Code provides: “Fraudulent
6 deceit. One who willfully deceives another with intent to induce him to alter his
7 position to his injury or risk, is liable for any damage which he thereby suffers.”
8 Cal. Civ. Code. § 1709.

9 823. Section 1710 of the California Civil Code provides: “Deceit, what. A
10 deceit, within the meaning of the last section, is either: 1. The suggestion, as a fact,
11 of that which is not true, by one who does not believe it to be true; . . . 3. The
12 suppression of a fact, by one who is bound to disclose it, or who gives information
13 of other facts which are likely to mislead for want of communication of that fact.”
14 Cal. Civ. Code. §§ 1710(1) & (3). “In California, the elements of the
15 misrepresentation torts (which are also denominated forms of “deceit”) are
16 prescribed by statute . . . and our common law tradition.” *Bily v. Arthur Young &*
17 *Co.*, 3 Cal. 4th 370, 414, 834 P.2d 745 (1992) (citing Cal. Civ. Code § 1710).

18 824. Defendants violated their general duty not to actively deceive, have
19 made knowingly false statements and have omitted and/or concealed information
20 which made statements Defendants did make knowingly false. Defendants acted
21 intentionally and/or unlawfully.

22 825. As alleged herein, Defendants made false statements regarding their
23 compliance with state and federal law regarding their duties to prevent diversion,
24 their duties to monitor, report and halt suspicious orders, and/or concealed their
25 noncompliance with these requirements.

26 826. As alleged herein, the Manufacturer Defendants engaged in false
27 representations and concealments of material fact regarding the use of opioids to
28 treat chronic, non-cancer pain.

1 827. As alleged herein, the Defendants knowingly and/or intentionally
2 made representations that were false. Defendants had a duty to disclose material
3 facts and concealed them. These false representations and concealed facts were
4 material to the conduct and actions at issue. Defendants made these false
5 representations and concealed facts with knowledge of the falsity of their
6 representations, and did so with the intent of misleading The County, Plaintiffs'
7 Community, the public, and persons on whom The County relied.

8 828. These false representations and concealments were reasonably
9 calculated to deceive The County, Plaintiffs' Community, and the physicians who
10 prescribed opioids for persons in Plaintiffs' Community, were made with the intent
11 to deceive and induce reliance, and did in fact deceive these persons, The County,
12 and Plaintiffs' Community.

13 829. The County, Plaintiffs' Community, and the physicians who
14 prescribed opioids reasonably relied on these false representations and
15 concealments of material fact.

16 830. The County justifiably relied on Defendants' representations and/or
17 concealments, both directly and indirectly. The County's injuries were proximately
18 caused by this reliance.

19 831. The injuries alleged by The County herein were sustained as a direct
20 and proximate cause of the Defendants' fraudulent conduct.

21 832. The County seeks economic losses (direct, incidental, or consequential
22 pecuniary losses) resulting from Defendants' fraudulent activity, including
23 fraudulent misrepresentations and fraudulent concealment.

24 833. The County seeks all legal and equitable relief as allowed by law,
25 except as expressly disavowed herein, including *inter alia* injunctive relief,
26 restitution, disgorgement of profits, compensatory damages and punitive damages,
27 and all damages allowed by law to be paid by the Defendants, attorney fees and
28 costs, and pre- and post-judgment interest.

COUNT VIII
UNJUST ENRICHMENT
(Against All Defendants)

834. Plaintiff, The County, incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

835. Defendants have unjustly retained a benefit to The County's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience. *Peterson v. Cellco Partnership*, 164 Cal. App. 4th 1583, 1593, 80 Cal. Rptr. 3d 316, 323 (2008); *Lectrodryer v. SeoulBank*, 77 Cal. App. 4th 723, 726, 91 Cal. Rptr. 2d 881 (2000).

836. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Plaintiffs' Community, including from opioids foreseeably and deliberately diverted within and into Plaintiffs' Community.

837. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

838. The County has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

839. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

840. These expenditures have helped sustain Defendants' businesses.

841. The County has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

842. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

1 843. The County has paid for the cost of Defendants' externalities and
2 Defendants have benefited from those payments because they allowed them to
3 continue providing customers with a high volume of opioid products. Because of
4 their deceptive marketing of prescription opioids, Manufacturer Defendants
5 obtained enrichment they would not otherwise have obtained. Because of their
6 conscious failure to exercise due diligence in preventing diversion, Defendants
7 obtained enrichment they would not otherwise have obtained. The enrichment was
8 without justification and the County lacks a remedy provided by law.

9 844. Defendants have unjustly retained benefits to the detriment of the
10 County, and Defendants' retention of such benefits violates the fundamental
11 principles of justice, equity, and good conscience.

12 845. Defendants' misconduct alleged in this case is ongoing and persistent.

13 846. Defendants' misconduct alleged in this case does not concern a
14 discrete event or discrete emergency of the sort a political subdivision would
15 reasonably expect to occur, and is not part of the normal and expected costs of a
16 local government's existence. The County alleges wrongful acts which are neither
17 discrete nor of the sort a local government can reasonably expect.

18 847. The County has incurred expenditures for special programs over and
19 above its ordinary public services.

20 848. By reason of Defendants' unlawful acts, The County has been
21 damaged and continues to be damaged, in a substantial amount to be determined at
22 trial.

23 849. The County seeks an order compelling Defendants to disgorge all
24 unjust enrichment to the County; and awarding such other, further, and different
25 relief as this Honorable Court may deem just.

PUNITIVE DAMAGES

1 850. Plaintiffs incorporate by reference all other paragraphs of this
2 Complaint as if fully set forth herein, and further alleges as follows.

3 851. By engaging in the above-described intentional and/or unlawful acts
4 or practices, Defendants acted maliciously towards Plaintiffs and with an
5 intentional disregard of the Plaintiffs' rights and the safety of Plaintiffs'
6 Community. Defendants acted oppressively, with conscious disregard for the rights
7 of others and/or in a reckless, wanton, willful or grossly negligent manner.
8 Defendants acted with a prolonged intentional disregard to the adverse
9 consequences of their actions and/or omissions. Defendants acted with a conscious
10 disregard for the rights and safety of others in a manner that had a great probability
11 of causing substantial harm. Defendants acted toward The County with malice and
12 were grossly negligent in failing to perform the duties and obligations imposed upon
13 them under applicable federal and state statutes and common law.

14 852. Defendants also committed fraud by knowingly and intentionally
15 making representations that were false. Defendants had a duty to disclose material
16 facts and concealed them. These false representations and concealed facts were
17 material to the conduct and actions at issue.

18 853. Defendants were selling and/or manufacturing dangerous drugs
19 statutorily categorized as posing a high potential for abuse and severe dependence.
20 Thus, Defendants knowingly traded in drugs that presented a high degree of danger
21 if prescribed incorrectly or diverted to other than legitimate medical, scientific or
22 industrial channels. Because of the severe level of danger posed by, and indeed
23 visited upon the State and Plaintiffs' Community by, these dangerous drugs,
24 Defendants owed a high duty of care to ensure that these drugs were only used for
25 proper medical purposes. Defendants chose profit over prudence and the safety of
26 the community, and an award of punitive damages is appropriate as punishment and
27 a deterrence. Punitive damages should be awarded pursuant to the common law and
28 Cal. Civ. Code § 3294.

854. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and gross negligence and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

RELIEF

WHEREFORE, Plaintiffs respectfully pray that this Court grant the following relief:

855. Entering Judgment in favor of The County in a final order against each of the Defendants;

856. Declare that Defendants have created a public nuisance in violation of California Civil Code Sections 3479 and 3480;

857. Enjoin the Defendants from performing any further acts in violation of California Civil Code Sections 3479 and 3480;

858. Order Defendants to fund an “abatement fund” on behalf of The People for the purposes of prospectively abating the ongoing opioid nuisance;

859. Order that Defendants compensate The County for damages to its property due to the ongoing public nuisance caused by the opioid epidemic;

860. Awarding actual damages, treble damages, injunctive and equitable relief, and forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to The County's racketeering claims;

861. Declare that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted in the dissemination of false and misleading statements in violation of the California False Advertising Act;

862. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in false advertising in violation of the California

1 False Advertising Act and ordering a temporary, preliminary or permanent
2 injunction;

3 863. Order Defendants to pay restitution to The People of any money
4 acquired by Defendants' false and misleading advertising, pursuant to the
5 California False Advertising Act;

6 864. Order Defendants to pay civil penalties to The People of two thousand
7 five hundred dollars (\$2,500) for each act of false and misleading advertising,
8 pursuant to Section 17536 of the California False Advertising Act;

9 865. Awarding The County the damages caused by the opioid epidemic,
10 and their negligent misrepresentations, fraud and deceit, including (A) costs for
11 providing medical care, additional therapeutic and prescription drug purchases, and
12 other treatments for patients suffering from opioid-related addiction or disease,
13 including overdoses and deaths; (B) costs for providing treatment, counseling, and
14 rehabilitation services; (C) costs for providing treatment of infants born with
15 opioid-related medical conditions; (D) costs for providing care for children whose
16 parents suffer from opioid-related disability or incapacitation; and (E) costs
17 associated with law enforcement and public safety relating to the opioid epidemic;

18 866. Enter a judgment against the Defendants requiring Defendants to pay
19 punitive damages to Plaintiffs;

20 867. Granting The County:

- 21 1. The cost of investigation, reasonable attorneys' fees, and all costs and
22 expenses;
 - 23 2. Pre-judgment and post-judgment interest; and,
 - 24 3. All other relief as provided by law and/or as the Court deems
25 appropriate and just.
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1 Dated: May 8, 2018

RESPECTFULLY SUBMITTED:

2 THE PEOPLE OF THE STATE OF
3 CALIFORNIA, COUNTY OF YUBA,
4 By Courtney Abril, OFFICE OF THE
5 COUNTY COUNSEL,
6 YUBA COUNTY, CALIFORNIA,
7 Plaintiffs

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